

## **Justification for Nonmaterial/Non-substantial Change request National HIV Surveillance System (NHSS) OMB #0920-0573**

This non-substantial change to the information collection request (ICR) for the National HIV Surveillance System (NHSS) OMB #0920-0573. Specially, we are requesting modifications to the Standards Evaluation Report (SER) to align with needed information to assess program performance in January 2024. All changes are minor edits to update years and rearrange sections for clarity. Changes are noted in *Justification for Nonmaterial/Non-substantial Change* request and the specific changes are outlined in **Attachment 1: Summary of Proposed Changes** along with **Attachment 2: SER**(track change). The final changes have placed in **Attachment 3(d)Annual Reporting: Standards Evaluation Report (SER)** instrument. This information will be captured via REDCap, a secure web application for building and managing online surveys and databases.

**National HIV Surveillance System (NHSS)**

**OMB # 0920-0573**

**Supporting Statement Part A**

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**Goal of the Project:** The NHSS is the primary source of population-based information on persons living with HIV in the United States and U.S. dependent areas. The NHSS collects information across the spectrum of HIV disease from HIV diagnosis, to AIDS, the end-stage disease caused by infection with HIV, and death.

**Intended use of resulting data:** NHSS data are used to monitor HIV trends, estimate HIV incidence and prevalence; examine patterns in HIV drug resistance and genetic diversity; detect HIV clusters; and describe characteristics of infected persons and perinatally exposed infants. Data are also used for surveillance-initiated investigations of persons identified as not-in-care to provide linkage to needed HIV medical care and services. NHSS data are used widely at the federal, state, and local levels for planning prevention programs and health-care services, and to allocate funding for prevention and care. In this Revision, CDC proposes updates to the adult case report form and pediatric case report forms used for reporting cases and exposures that will strengthen uses of NHSS data to guide HIV prevention, care and control efforts.

**Methods to be used to collect:** Laboratories and health care providers collect data using standard report forms and submit reports to health departments in both paper and electronic formats as required by their jurisdictions. Data are collected on persons who meet CDC's laboratory and clinical criteria for HIV surveillance case definition. De-identified data are then reported electronically from health departments to CDC via the secure access management system (SAMS).

**The subpopulation to be studied:** The NHSS includes adults/adolescents and children with HIV infection who meet the laboratory or clinical criteria for HIV in 50 states, the District of Columbia, and eight U.S. dependent areas. In addition, where reportable by law, rule, or regulation, information on infants born to HIV infected mothers is also reported.

**How the data will be analyzed:** Local health departments routinely review and analyze their data to monitor HIV trends, evaluate program success, monitor HIV clusters and assist in focusing resources to reduce the burden of HIV. CDC publishes annual surveillance reports summarizing national HIV statistics, updated fact sheets based on demographic and risk group, periodic supplemental surveillance reports, and also conducts special analyses for publication in peer-reviewed scientific journals to further describe and interpret national HIV data. Special analyses describe key trends, identify high risk groups, and assist in developing new and tailored prevention and treatment strategies. Data is publicly available for analysis at CDC NCHHSTP AtlasPlus which is an interactive tool that gives users the ability to create customized tables, maps, and charts using more than 15 years of CDC's surveillance data on HIV, viral hepatitis, sexually transmitted diseases (STDs), and tuberculosis (TB) and also provides access to indicators on social determinants of health allowing users to view social and economic data in conjunction with surveillance data for each disease.

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) requests a 3-year approval for revision to previously OMB-approved No. #0920-0573, expiration 11/30/2022, entitled "National HIV Surveillance System (NHSS)." Since the first human immunodeficiency virus (HIV) cases were recognized in the United States in 1981, CDC has collected national surveillance data on this important infectious disease. As the science and epidemiology of HIV disease has evolved, the surveillance system has been updated to meet the nation's needs for information (refer to regular renewals under OMB #0920-0573). The Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to acquired immunodeficiency syndrome (AIDS), the end-stage disease caused by infection with HIV, and death. In addition, the data collection provides the essential data used to calculate population-based HIV incidence and prevalence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of concern, and monitor perinatal HIV exposures. These data have been collected, maintained, and reported using standard report forms and software. Continued collection of NHSS data is necessary to monitor the impact of HIV disease and guide HIV prevention efforts in the United States. NHSS data are widely used at all government levels to assess the HIV infection morbidity and its impact on mortality, to allocate medical care resources and services, to guide prevention and disease control activities, and monitor progress toward achieving national prevention goals of the ending the HIV epidemic in the U.S. initiative ([Ending the HIV Epidemic in the U.S. \(EHE\) | CDC](#)).

NHSS data collection activities are currently supported through cooperative agreements with health departments under CDC Cooperative Agreements [PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments](#) and [PS20-2010 Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States](#), [PS18-1801 Accelerating the Prevention and Control of HIV/AIDS, Viral Hepatitis, STDs, and TB in the U.S. - Affiliated Pacific Islands](#) and [PS23-2302 Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S. Affiliated Pacific Islands](#). This information collection request revision includes activities to continue national surveillance program activities and align with program priorities of PS18-1802, PS20-2010, PS18-1801, PS23-2303 and any continuation of CDC funding or new CDC funding announced

for HIV surveillance or surveillance related activities over the next three years.

The data CDC collects through the NHSS provide the sole source of comprehensive, complete national HIV statistics collected in a timely and standardized manner. If HIV data are not collected, reliable and consistent information will not be available on the extent and distribution of the HIV disease burden in the United States. Federal health officials will not be able to efficiently detect and respond to cases of public health importance or changes in morbidity patterns, nor monitor success toward achieving national prevention goals. These surveillance data, together with behavioral data and other scientific information are the primary data used by state and local health departments in their prevention planning processes to make informed decisions about where and how to target resources locally. Effective assessment of federal, state, and local HIV prevention and control efforts, based on timely and standardized data, would not be possible without the collection of these data. Ultimately, the goal of preventing HIV in the United States cannot be achieved without a NHSS.

HIV surveillance data collection by CDC is authorized under Sections 317(k) (2) and 318(c) of the Public Health Service Act [42 U.S.C. Sections 247b (k) (2) and 247c(c)], as amended and Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) (Attachment 1).

## **2. Purpose and Use of the Information Collection**

The purpose of the information collected by NHSS is to monitor the scope of the HIV disease burden in the United States. Surveillance data are used to monitor HIV trends, estimate HIV incidence and prevalence; examine patterns in HIV drug resistance and genetic diversity; detect HIV clusters; and describe characteristics of persons with HIV infection diagnoses and perinatally exposed infants. Data are also used for surveillance-initiated investigations of persons identified as not-in-care to provide linkage to needed HIV medical care and services. These data are the primary population-based data source used to evaluate prevention and care programs and to focus prevention efforts at the national, state, and local levels. Data collected in the NHSS are critical for monitoring progress towards the goals of the [National HIV/AIDS Strategy for the United States \(NHAS\)](#) and [Ending the HIV Epidemic in the United States \(EHE\) initiative](#). Furthermore, these data are critical to accomplishing the CDC goal of reducing the HIV morbidity and mortality in the United States, increasing HIV testing, and address health inequities by eliminating racial and ethnic disparities.

Over the last forty years, the NHSS has been modified to respond to changes in the epidemiology of HIV and advances and improvements in surveillance practices, HIV testing technology, care, and treatment, incorporating reporting of HIV diagnoses, clinical indicators of disease progression, such as opportunistic infections, CD4 T-lymphocyte counts and percentages, HIV nucleotide sequences and HIV detection tests (e.g., quantitative viral load) and antiretroviral treatment history. These modifications have addressed changes in the surveillance case definition as well as changes in the data collection system to adjust for programmatic priorities. For example, changes proposed in this revision include additions of response options related to self-testing and HIV testing history variables to better characterize use of recently available self-testing technologies that have particularly increased in use during the COVID-19 pandemic. In addition, modification of the gender identity response options and collection of a new variable on sexual orientation proposed in this revision will allow CDC to better address HIV prevention needs of sexual minority populations (e.g., lesbian, gay, bisexual and transgender (LGBT)). Collection of information on antiretroviral use history allows for monitoring of pre-exposure prophylaxis (PrEP) among persons with diagnosed HIV, whereas HIV nucleotide sequence data allows determining transmission patterns, monitoring HIV drug resistance, and determine the geographic distribution of virus subtypes in the United States. These data will continue to support selection of diagnostic and clinical tests appropriate for use with various HIV-1 subtypes, and ultimately will inform the development of vaccines nationally. In addition, HIV nucleotide sequence data are being used to promptly detect recent, ongoing or rapidly growing transmission clusters to target prevention interventions. Health departments also use surveillance data to identify persons who may be in need of HIV medical care or services and link them to those services to ensure persons with HIV receive needed treatment and achieve viral suppression to ultimately prevent new infections.

#### *Adult and Pediatric Case Reports, Perinatal Exposure Reports and Related Activities*

Reporting of Adult and Pediatric cases are fundamental components of NHSS. Health departments compile clinical, behavioral, antiretroviral treatment history and laboratory test information (e.g., HIV tests, CD4) information reported from laboratories and care providers using standard forms, case definitions, and reporting software and report this information to CDC. HIV incidence is estimated by CDC using a statistical model (i.e., a CD4 Depletion model) without the need for additional data collection and will continue to be published in supplemental surveillance reports and other data products. Currently, all 50 states, D.C., Puerto Rico, U.S. Virgin Islands, American Samoa, Guam, Northern Mariana Islands, and the Republic of Palau mandate and collect confidential name-based surveillance data on HIV cases in

adults/adolescents and children using the HIV confidential case report forms and current case definition (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>). Over the next three years we anticipate that the Marshall Islands and the Federated States of Micronesia will also mandate collection of name-based HIV surveillance data and report those cases to CDC. Therefore, the estimated burden for the next three years is based on HIV case reporting in 59 areas including these jurisdictions.

In addition to adult and pediatric case reports, infants known to be HIV-exposed are monitored after birth up to 18 months of age to determine HIV infection status and progression to HIV, stage 3 (AIDS). The goals of perinatal HIV exposure reports are to continue to monitor and evaluate perinatal HIV transmission and evaluate prevention efforts in jurisdictions that have laws and regulations that allow for perinatal exposure reporting. Surveillance data collected as part of perinatal exposure reporting are critical for evaluating strategies to prevent perinatal transmission and ultimately improving the health of infants. NHSS has successfully monitored changes in perinatal transmission and treatment successes. In the United States mother-to-child HIV transmission has been drastically reduced, from a high of 2,500 new perinatal HIV infections in 1992 to fewer than 40 in recent years.

Data collection for perinatal HIV exposure reporting has become integrated with routine HIV case surveillance and includes medical record reviews of mother-infant pairs and follow-up of HIV exposed children. In this revision, we have discontinued the use of the previously approved Perinatal HIV Exposure Report (PHER) form and will continue data collection of perinatal exposures on the modified Pediatric HIV Confidential Case Report Form (PCRFF). The PHER form has been consolidated with the PCRFF to reduce redundancy across forms and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities.

Surveillance programs routinely update case report information, conduct case report evaluations, and conduct ongoing deduplication activities to ensure the accurate and high-quality data are reported to the national system and burden associated with these activities is included in the burden estimate. Case report forms include necessary elements for the surveillance definition and evaluation of HIV prevention and care programs. The revised forms submitted with this revision include changes to selected currently collected data elements on the Adult HIV Confidential Case Report form (ACRF) (**Attachment 3a**) and a consolidated PCRFF (**Attachment 3b**). Detailed description of the form changes are described in the Summary of Changes Document (**Attachment 10**) and **Section 15 Explanation for Program Changes or Adjustments**. The electronic reporting system allows jurisdictions flexibility in collecting information from multiple sources and for

repeated events required for monitoring the current HIV disease burden. The data elements of the software system are indicated in the variable list in **Attachment 3c**. The revisions to data elements proposed in this revision will be incorporated into the electronic reporting system (i.e. enhanced HIV/AIDS reporting system (eHARS) v4.13 to be released in 2023). The technical guidance for HIV Surveillance Programs has been revised to support the use of the new forms and the integration of case surveillance and perinatal exposure reporting activities. (**Attachments 4 a,b,c**)

### *Investigation Reporting and Evaluation*

Health departments use the absence of reported test results to HIV surveillance programs to identify persons who may not be in HIV medical care and who may be in need of other services and to link those individuals to needed care and services. This revision includes estimated burden for health departments reporting of these variables, and for interventions to link people to care. This information is primarily imported electronically from other data systems used to manage these activities in the health departments. A logic model for the Data to Care strategy of identifying persons with diagnosed HIV who are not in HIV medical care and linking them to care and guidance for reporting and evaluation of Data to Care not-in-care investigations is included in **Attachment 4(d)**. More information on the Data to Care strategy can be found at [Data to Care | Treat | Effective Interventions | HIV/AIDS | CDC](#).

HIV sequence data that are generated from drug resistance testing performed as part of routine HIV medical care are routinely reported to health departments. Using methodology developed by CDC, HIV surveillance data can be analyzed to identify clusters of likely recent and rapid transmission, and ultimately guide the implementation of prevention efforts. Clusters can be identified through analysis of surveillance data including HIV sequence data (e.g., molecular clusters) or diagnosis data (e.g., time-space clusters represent an increase in the number of diagnoses of HIV infection in a particular geographic area above levels expected given previous patterns). In addition, clusters can also be identified via notification by partner services staff, or notification by astute clinical providers or frontline staff at health departments. Cluster investigation variables may be electronically imported from other systems that may be used by health departments and will assist in the overall monitoring and evaluation of cluster investigations. We have included burden of reporting for the estimated subset of persons identified as part of clusters. The additional estimated burden for both cluster investigations and data to care investigations are included in the burden table under Investigation reporting and evaluation. Guidance for Detecting HIV transmission clusters is provided in **Attachment 4 (e)**. Additional information and guidance on HIV cluster and detection

response is available at:

<https://www.cdc.gov/hiv/programresources/guidance/cluster-outbreak/index.html>

### *Cluster Reports*

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed in order to intervene to interrupt ongoing transmission and prevent future HIV infections. Health departments may detect clusters through multiple means, as described above. Data on clusters of recent and rapid HIV transmission in the United States will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. It is necessary and important for CDC to collect this information to monitor cluster detection and response activities that are required of all 59 jurisdictions funded under an Integrated HIV Surveillance and Prevention Programs for Health Departments cooperative agreement.

These data will be collected through quarterly cluster report forms **(Attachments 3e, 3f, 3g)** that will be completed by jurisdictions for clusters that they have identified and for which they are actively conducting response activities. The 'initial cluster report form' **(Attachment 3(e))** will be completed in the quarter a cluster is first identified. This form includes questions about the means of cluster detection, data reviewed to assess the cluster, the size of the cluster and outcomes of routine public health investigations ('partner services'), key findings about the cluster from existing data review, and the jurisdiction's assessment of their level of concern for the cluster. The 'cluster follow up form' **(Attachment 3(f))** will be completed each quarter in which the cluster response remains active. This form includes questions about the current cluster size, outcomes of HIV testing conducted in response to the cluster, and the jurisdiction's updated assessment of their current level of concern for the cluster. The 'cluster close-out form' **(Attachment 3(g))** will be completed when cluster response activities are closed, or at annual intervals while cluster response remains active. This form includes questions on summary outcome measures of response activities, including HIV testing conducted in response to the cluster, PrEP referral, and linkage-to-care efforts. It includes additional questions on activities conducted in response to the cluster, and key findings and impacts of the response. Data from individual cluster report forms will be aggregated at the national level to summarize activities and assess outcomes of cluster response activities at a national level.

Completion of forms will be determined by the number of clusters detected. Jurisdictions without any identified clusters will not complete any, while jurisdictions that may detect multiple clusters will complete multiple cluster report forms. Health departments will



transmit these forms to CDC using CDC's Secure Access Management System (SAMS). Instructions for completing the cluster forms are provided in **Attachment 4(f)**.

### *Standards Evaluation Report (SER)*

The annual information collected on laboratory data and data quality measures as part of the SER (**Attachment 3(d)**) are used to ensure the accuracy, timeliness, and completeness of the national HIV surveillance data which are widely used and disseminated and critical for monitoring and evaluating the program objectives of PS18-1802, PS20-2010 and the national prevention goals. Minor non-substantial edits in wording for clarity and deletion of several questions that are no longer needed are proposed in this revision which will be used for reporting in 2023.

### *Data Use and Dissemination*

Reporting areas routinely review and analyze their data to monitor local HIV trends, evaluate program success, and assist in focusing resources to reduce the burden of HIV. CDC publishes annual surveillance reports summarizing national HIV indicators (see **Attachment 5**), updated fact sheets based on demographic and priority populations, periodic supplements to the surveillance reports, and periodically special analyses in peer-reviewed scientific journals to further describe and interpret national HIV data. Analyses describe key trends, identify high priority populations, and assist in developing new prevention and treatment strategies. The annual report is disseminated to the public, state and city health officers, infectious disease experts, and others concerned with HIV control and prevention. The surveillance report, supplemental reports on various topics of interest, accompanying slide sets, fact sheets, and other important publications from the HIV surveillance system are posted on the DHP website at: [HIV Surveillance | Reports | Resource Library | HIV/AIDS | CDC](#). The [NCHSTP Atlas Plus](#) is a publicly available interactive tool that provides CDC an effective way to disseminate data, while allowing users to observe trends and patterns by creating detailed reports, maps, and other graphics. The Atlas provides interactive maps, graphs, tables, and figures showing geographic patterns and time trends of HIV, AIDS, chlamydia, gonorrhea, primary and secondary syphilis surveillance data, TB and viral hepatitis. Surveillance data are also used to track progress of the EHE indicators aimed at having greatest effect on the HIV in the United States and is available on [The America's HIV Epidemic Analysis Dashboard \(AHEAD\)](#). Data collected as part of the NHSS are essential for monitoring the progress toward achieving these national objectives in the coming years. A supplemental report illustrating how data from the NHSS can be used to assess progress on selected national care



objectives was published in May 2022. (Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. *HIV Surveillance Supplemental Report* 2022;27(No. 3). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>). Published May 2022. Accessed [June 2, 2022]). CDC also uses national surveillance data to respond to special data requests to assist other government agencies, Congress, and organizations with HIV control and prevention activities.

The surveillance report published in 2022, shows the overall number of HIV diagnoses in the United States in 2020 (30,403) was 17% lower than in 2019 (36,585). The steep reduction in diagnoses in 2020 is likely due to disruptions in clinical care services, patient hesitancy in accessing clinical services and shortages in HIV testing reagents/materials, which causes concerns regarding underdiagnosis. In 2020, there were 30,692 diagnoses of HIV infection in the United States and 6 dependent areas. At the end of 2020, 1,072,051 persons in the United States and 6 dependent areas were living with diagnosed HIV infection, whereas 18,493 persons with HIV died for an overall death rate of 5.6 per 100,000. A total of 32 children born during 2019 in the United States, received a diagnosis of HIV infection attributed to perinatal transmission. (Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. *HIV Surveillance Supplemental Report* 2022;27(No. 3). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2022. Accessed [June 2, 2022]). From 2016 through 2019 in the U. S. and Puerto Rico, among the 11,757 children born who were exposed but not perinatally infected with HIV, 82% were born to mothers who were tested before pregnancy and 15% were born to mothers who were tested during pregnancy. (Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2020; vol. 33. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2022. Accessed [June 2, 2022])

The COVID-19 pandemic impacted the HIV surveillance activities and HIV testing in the United States during 2020 making 2020 data unsuitable for trends assessment. CDC most recent publication of HIV incidence and prevalence estimates in the United States describing trends from 2015-2019 is available at: Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2015–2019. *HIV Surveillance Supplemental Report* 2021;26(No. 1). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021. Accessed [June 2, 2022].

HIV surveillance data assists federal, state, and local public health officials and policy makers in program planning, evaluation, and resource allocation. Currently, HIV and AIDS case data are used to guide the distribution of funds for many federal programs as well as programs at the state and local level that assist persons living with HIV. The largest of these include programs funded under the Ryan White

HIV/AIDS Program which funds treatment and care for persons with HIV who could not otherwise afford expensive, life-saving therapies. HIV surveillance data provided for the Ryan White HIV/AIDS Program for fiscal year 2021 is summarized in supplemental report Centers for Disease Control and Prevention. HIV and AIDS data through December 2019 provided for the Ryan White HIV/AIDS Program, for fiscal year 2021. HIV Surveillance Supplemental Report 2022;27(No. 1:[1-17].<http://www.cdc.gov/hiv/library/reports/hivsurveillance.html>. Published January 2022. Accessed [June 2, 2022]. HIV surveillance data are also provided to the office of Housing and Urban Development (HUD) for allocations for HIV services under the Housing Opportunities for Persons with AIDS (HOPWA) program. The continued use of HIV data to guide funding of these important care, services, and housing programs make the continued collection of high-quality data through the NHSS critical.

### **3. Use of Improved Information Technology and Burden Reduction**

To reduce burden for respondents, the HIV surveillance system is based on electronic data management and transmission systems. Since the first cases of AIDS were recognized and states began to report cases through standard case reporting methods, the surveillance system has been modified to support changing needs for data and to improve the efficiency of data collection. DHP has encouraged the use of electronic reporting methods and provided state health departments with data management software to reduce reporting burden.

The electronic reporting system currently used is an application for collecting, storing, and sending data to CDC and is necessary to monitor the HIV disease burden and to conduct systematic evaluations of HIV surveillance programs. The enhanced HIV/AIDS reporting System (eHARS), first deployed in 2005 and updated periodically, aims to ease electronic reporting and streamline use of alternate databases that may be used by health departments to manage incoming reports from various sources. For example, health departments may maintain a separate alternate database for managing laboratory reports which will be entered into the electronic reporting system. The electronic reporting system works with SQL to enable powerful data manipulation. Using ad hoc reporting, SAS, and other tools, NHSS data can be queried, filtered, joined, and then exported to Excel, Access, or other software applications for additional reporting and analysis. The electronic reporting system application enables project areas to collect, manage, analyze, disseminate, and report to CDC the data needed to monitor and track the HIV disease burden on both local and national levels. The electronic reporting system provides project areas with the tools needed to follow CDC technical guidance for HIV surveillance. Since full deployment of the electronic reporting system CDC's emphasis has been on assisting the project areas in maximizing

the use of the surveillance data, through provision of SAS programs and other tools and technical guidance. Updates to the software are made one to two times per year, usually to reflect updated business requirements for surveillance practices, updated HIV case definition, new laboratory testing algorithms, or other enhancements or problem solving improvements. The next release of the enhanced HIV/AIDS reporting system (eHARS) v4.13 which will align with case report form changes in this revision is anticipated for release in 2023. DHP is joining agency wide data modernization efforts aimed at modernizing data systems and anticipates taking steps toward updating HIV surveillance systems to align with agency efforts over the next 3 years.

Data is increasingly obtained from electronic data sources to complete cases reports, particularly from laboratories. However, a laboratory report alone does not typically contain all of the required data elements to complete a case report and usually requires additional follow-up activities such as medical record review, telephone contact, or local database abstraction. Most surveillance programs import electronic laboratory test results into the reporting system. The electronic reporting system provides tools to facilitate the import and use of electronic data sources and enhance the use of electronic health information for case reporting. All case reports (100%) are entered and reported by health departments (who serve as the respondents for this data collection) using the electronic reporting system, and data are reported to CDC in encrypted electronic format. Information for the Standards Evaluation Report (SER) and Cluster Report Forms are also entered and reported in electronic format to reduce reporting burden. All data are reported securely to CDC via the Secure Access Management System (SAMS). The Division of HIV Prevention is engaged in CDC Data Modernization Initiative (DMI) and plans to align the HIV surveillance systems with DMI goals.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The data collected by the NHSS provide the sole source of comprehensive, complete national HIV statistics collected in a timely and standardized manner. Literature searches, attendance at national HIV meetings/conferences, discussions with officials from state and local health departments and ongoing consultations with HIV experts nationwide, continue to support that these data are unique and are not available from any other source within the federal government or from non-federal sources. HIV surveillance has come to be relied on as the only nationally representative data source on which to base the equitable distribution of resources for HIV patient care and management. HIV surveillance data is the primary source for identifying priority geographic locations to focus cross agency resources to end HIV and to monitor progress on the Ending the HIV Epidemic initiative (see the [America's HIV Epidemic Analysis Dashboard](#)

[\(AHEAD\)](#). In addition, HIV surveillance data is a primary source for detection of molecular and time space HIV clusters and CDC has collaborated with health departments and health partners to develop guidance and resources for use of data for [HIV cluster detection and response](#) activities.

## **5. Impact on Small Business or Other Small Entities**

Data collection and electronic submissions to CDC from the reporting areas are done by HIV surveillance programs in state and local health departments funded by CDC to conduct these activities. Laboratories and care providers are required to report cases of HIV and AIDS in accordance with local disease reporting laws, rules and regulations. Health departments compile reported information and are the respondents for this surveillance system. No small businesses or small entities are directly involved in reporting these data collection to CDC.

## **6. Consequences of Collecting the Information Less Frequently**

CDC requests that reporting areas send their adult, pediatric and perinatal exposure report data electronically on a monthly basis. While the other data collection forms in this ICR are requested less frequently (e.g., SER is reported annually, cluster forms are reported quarterly). The goal of the monthly transfer schedule is to finalize quality quarterly data sets within four to six weeks after the close of the quarters. This transfer schedule has facilitated keeping the reporting area and CDC databases up to date and ensured timely and accurate assessments of trends. Through timely data provided by the NHSS, CDC can determine the variability by region, state, risk group, and racial/ethnic groups; more accurately track new infections; and use that information to better evaluate and target prevention programs and direct resources for care services.

This reporting schedule has also enabled DHP to evaluate data quality on an ongoing basis to efficiently detect, investigate, and resolve data issues with the reporting areas. DHP periodically discusses the frequency of electronic data transmission with reporting areas to determine the optimum frequency to keep respondent burden low while still allowing prompt identification of changes in HIV trends. Less frequent transmission would impede the ability of CDC to maintain an accurate and timely database. There are no legal obstacles to reduce the burden.

## **7. Special Circumstances relating to the Guidelines 5 CFR 1320.6**

Collection of HIV data is conducted in a manner consistent with the guidelines in 5 CFR 1320.6. DHP requests that reporting areas send encrypted data via the secure access management system (SAMS) on a

monthly basis for adequate and timely tracking of disease trends. Further description of this process and justification are described in A.6.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A. The 60-Day FRN was published in the *Federal Register* on April 1, 2022, Volume 87, Number 63, Pages 19097-19100 (**Attachment 2a**). CDC received two public comments in support of proposed changes. (**Attachments 2b,c**). The Williams Institute at the UCLA School of Law wrote in support of the additional measure of sexual orientation and maintaining the measure of gender identity (as proposed). They stated that the proposed changes are 1) consistent with the mission and purposes of CDC and NHSS; 2) needed to provide better quality data to achieve prevention goals of ending the HIV epidemic initiative and provide information to better focus research and prevention efforts for LGBT people living with HIV; and 3) consistent with existing research on sexual orientation and gender identity (SOGI) measurement. The additional comment received also wrote in support of the changes proposed citing that the proposed changes would better meet current data needs related to SOGI and to rapid development of test technologies and the associated test history. In addition, the changes would improve the formatting and usability of surveillance forms that would serve to ease the data collection process and would ultimately provide more comprehensive data to monitor the burden of HIV in the United States. Both comments emphasized the need for continued privacy protections and related training for staff involved in surveillance activities. CDC acknowledged the comments and provided letters of response. No actions by the agency were necessary and no changes to the burden hours or costs were required in response to the comments received.

B. Consultation with state, local, and territorial HIV surveillance coordinators, and other HIV specialists occurs on a regular basis through national HIV surveillance monthly calls and webinars, routine site visits, periodic conference calls with HIV surveillance coordinators, CSTE HIV subcommittee leadership and members, and national conferences. These discussions allow CDC to obtain information on the availability of data, frequency of data collection, clarity of instructions, and record keeping, reporting format, and key data elements. During these meetings data collection and evaluation activities are discussed and training offered on aspects of surveillance data collection and use. In July 2021, proposed changes to the data collection forms and software were reviewed with partners and HIV surveillance coordinators during national calls and changes were incorporated as needed based on feedback received. An NHSS HIV Technical Assistance Meeting was held June 12-13, 2019. During 2020 no in-person technical assistance meeting was scheduled due to Covid-19 restrictions. However, during 2020 the HIV Surveillance Branch

continued with monthly national NHSS support and NHSS data systems and laboratory support calls with state and local HIV surveillance staff. Technical assistance meetings resumed in 2021 and were conducted in a series of virtual meetings held in 2021 (8 sessions March through May 3/30, 4/6, 4/13, 5/4, 5/11, 5/18) and 2022 (7 sessions May through June 5/3, 5/10, 5/17, 5/24, 5/31, 6/7, 6/14). CDC plans to continue to sponsor these national technical assistance meetings on an annual or biannual basis.

A series of virtual meetings and community engagement webinars were conducted in 2018 and 2019 to discuss implementation of cluster detection and response activities with community members, public health departments, community-based organizations, academics, and public health partners. These meetings focused on engaging communities, of providing information on proposed cluster response activities, discussion of ethical implementation, discussion of the impact of laws and policies, and discussion of data sharing and release issues. In addition, CDC participated in or hosted at least 5 engagements in 2021 and 18 in 2022 to discuss implementation of cluster detection and response activities with public health partners, providers, and community-based organizations, including one 1.5 day-long session hosted by the Presidential Advisory Committee on HIV/AIDS (PACHA) Stigma and Disparities Subcommittee. Other engagements included audiences of HIV care providers, health departments, and other partners and ranged from 7 to over 350 attendees. Overall goals for these discussions were aimed at increasing understanding of community concerns, increasing awareness of HIV surveillance and cluster detection and response activities, and assisting in the development of implementation guidance.

## **9. Explanation of Any Payment or Gift to Respondents**

The respondents for this ICR are health departments that are funded through CDC cooperative agreements to conduct HIV surveillance activities. There are no other provisions for payments or gifts to respondents.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The NCHHSTP PRA Coordinator has determined that the Privacy Act applies to this information collection. Personally identifiable information (PII) is being collected. A Privacy Impact Assessment for the electronic reporting system was approved May 18, 2020 (**Attachment 6(a)**) and **Attachment 6 (b)** provides the authorization to operate. The applicable system of records notice (SORN) is 09-20-0136.

Reporting of HIV case data is required under state laws and regulations for notifiable disease reporting. These data are reported

without consent of the individual by health care providers and laboratories to state or local health departments or through abstraction of medical records by health department personnel. Data are reported voluntarily by state and local health departments to CDC and these activities are supported through cooperative agreements.

HIV surveillance data are collected under an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act (42 USC 242m(d))(**Attachment 7(a)**). The Assurance applies both to individual patients who are the subject of this data collection, and to the organizational respondents that support the surveillance system by collecting data. Information collected in the HIV surveillance system that would permit direct or indirect identification of any individual or establishment is collected with a guarantee that it will be held in confidence, that it will be used only for purposes stated in the Assurance, and that it will not otherwise be disclosed or released without the consent of the individual or the establishment in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m(d)).

Case reports are completed by local health care service providers and laboratories and transmitted to state and local health departments by U.S. mail, secure fax (CDC security and confidentiality guidance discourages this practice) or secure electronic transfer. In some instances, health department staff complete the forms. Data are then compiled by health departments that serve as the respondents for the HIV surveillance system and forwarded to CDC. Although identifiable patient-level case report data are collected by local health departments the case report data are de-identified before they are transmitted to CDC.

The Adult and Pediatric HIV Confidential Case Report Forms include a header that contains patient identifiers (e.g., name, address, and telephone number). The header feature allows health department personnel to verify the identity of each patient (and associated patient-level information) reported to the surveillance system, and to conduct public health follow-up. Other PII include date of death. Date of birth and date of death information are forwarded to CDC together with other case information after names and street addresses are removed. Demographic information such as sex, sexual orientation(proposed), age at diagnosis, vital status, country of birth, residence, race and ethnicity are also collected.

Upon receipt of the case report forms, the health department assigns one or two unique codes to each case report: the State Patient Number and/or the City/County Patient Number. Names entered into the system are converted by the software to a soundex code. The data files submitted electronically to CDC contain only the last name soundex code and state assigned patient numbers, and date of birth and not the directly identifiable information contained in the header. Case



information including personal identifiers is retained in the health departments' local electronic reporting system indefinitely in a cumulative database.

Areas use a software system developed by CDC to store and analyze data, as well as transmit de-identified encrypted data to CDC. Since April 2004, all health departments have been required to forward data to CDC electronically through a secure encrypted process. The current method is the Secure Access Management System (SAMS). The SAMS uses digital certificate technology to create a Secure Sockets Layer (SSL) or encrypted tunnel through which data are transmitted to CDC.

Because sensitive data are collected as part of HIV surveillance, steps are taken at every stage of data collection, storage, and use to ensure that data are secured and confidentiality and privacy are maintained. Various state laws and regulations protecting data collected and stored by health departments as part of public health surveillance exist. In addition, policies delineating security and confidentiality practices and data release exist at the state and local health department and CDC levels serving to further protect HIV surveillance data. As a condition of funding under the HIV surveillance cooperative agreements, health departments must certify annually that they comply with security and confidentiality program requirements outlined in the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. Centers for Disease Control and Prevention; 2011 available at:

<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf> (**Attachment 8**). The guidelines include detailed requirements to address areas of physical and electronic security, development of policies, training, data access controls, data security, and secure data transfer and storage, and guidance on development of data sharing plans.

NCHHSTP Data security and confidentiality guidelines specify data are required to be kept in a physically and technically secure environment, with limited access by a minimum number of authorized individuals. Paper documents related to case reports are required to be kept in locked filing cabinets within a secure area. State and local health departments follow local schedules for archival and destruction of paper copies of case reports. Persons with authorized access are required to attend local security training annually and be individually responsible for protecting their own workstations. Confidential surveillance data must be encrypted before electronic transfer and ancillary databases or other electronic files containing confidential data also need to be encrypted when not in use. Additionally, areas must have written policies and procedures. These policies and procedures include steps that would be taken if a breach



were to occur. Staff sign non-disclosure agreements or confidentiality statements annually that outline staff responsibilities and possible penalties if a breach were to occur. CDC reviews procedures for protecting the confidentiality and security of HIV surveillance data through periodic site visits and as part of the annual renewal of cooperative agreements for HIV surveillance.

Data maintained at CDC are stored on a secure server with limited access. Steps are taken to limit access to the national database to those authorized by the Chief of the HIV Surveillance Branch. All staff authorized to access CDC databases must complete annual security and confidentiality training, be familiar with Branch and CDC data release policies and procedures and sign non-disclosure agreements. These and additional steps taken by CDC to secure the data are described in detail in the Confidentiality Security Statement for the National Human Immunodeficiency Virus (HIV) Surveillance System (NHSS) and Surveillance-related Data (including surveillance information, case investigations, supplemental surveillance projects, research activities, and evaluations (**Attachment 7(b)**)).

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

HIV surveillance data including data collected for adult/adolescent and pediatric case reporting, surveillance evaluations and cluster detection and response, and perinatal exposure reporting have been determined to be non-research, routine disease surveillance activities/public health program activities by NCHHSTP/CDC and IRB approval is not required (see **Attachment 9**).

Sensitive information, including information on sexual or drug using behaviors that may be related to HIV transmission is collected as part of HIV surveillance. Risk factors for transmission of HIV include behaviors which are sensitive and, in some cases, illegal (e.g., substance abuse). However, these data are critical for monitoring patterns of transmission and are important for understanding and describing risk behaviors associated with HIV infection. CDC uses these data to describe epidemiologic trends by risk behavior. These data are also used extensively by community prevention planning groups to help target prevention activities at the local level. For example, these data may be used to target community-based HIV testing programs or HIV-related care services. The value of HIV surveillance data is greatly diminished without sufficient information to determine whether persons have engaged in recognized or potential risk behaviors, including sexual behaviors and illicit use of drugs.

Race and ethnicity data are also collected as part of HIV surveillance and may be considered sensitive, but are critical for describing epidemiologic trends, focusing prevention efforts and to monitor and

ensure health equity. The data collection forms adhere to OMB standards for the classification of federal data on race and ethnicity, collecting race and ethnicity separately, collecting multiple races and disaggregating Asian/Pacific Islander into two categories: Asian and Native Hawaiian/Other Pacific Islander.

Information on sexual orientation and gender identity may also be considered sensitive but are critical for monitoring the impact of HIV on sexual minorities and focusing prevention efforts. Collection of sexual orientation information is supported by organizations specializing in addressing the needs of sexual minorities and supported by Health People 2030, and the National Academy of Medicine. Further, the data collected is consistent with existing practices of CDC and other federal agencies, reflects recommendations from health departments collecting these data and other data collection systems.

The pediatric case report form used for pediatric and perinatal HIV exposure reporting data collection asks for maternal history, including questions about the mother's drug use behavior, prenatal care, receipt of antiretroviral treatment during pregnancy, and other antiretroviral treatment. These questions are asked in part because the mother's medical history/receipt of antiretroviral medicines affects the health outcomes, medical care and treatment the infant should receive. Collection of medical history and behavioral information on mothers and their exposed infants is critical for continued monitoring and refinement of HIV prevention and treatment guidelines for pregnant women and their children and to achieve HIV perinatal transmission elimination goals.

Finally, some clinical and laboratory markers of HIV infection may also be considered sensitive. Fears remain regarding potential stigma associated with HIV infection and its potential impact on employability or insurability and the potential for release for non-public health purposes under state HIV criminal laws. However, laboratory test data related to a person's HIV positive status or tests indicative of disease progression are needed to monitor trends in HIV diagnosis and describe the spectrum of HIV-related morbidity over time. CDC uses these core data elements to profile the HIV disease burden in the United States and local areas use these data extensively to monitor local disease trends. In addition, HIV sequence data is increasingly being used to identify clusters of recent and rapid transmission and prompt follow-up by health departments. The collection of clinical and laboratory data are the cornerstone of our surveillance system and central to monitoring the HIV disease burden and evaluating progress towards national HIV prevention goals.

CDC and state health departments have data release policies that restrict the release of information that could indirectly or directly identify an individual. Data released by CDC are typically in aggregate format with cell size restrictions. CDC in collaboration

with the Council of State and Territorial Epidemiologists revised data re-release agreements with states that specify the geographic level at which their data can be released. The current data release policy and agreements to abide by restrictions on data release for CDC staff are included with the Assurance of Confidentiality Security Statement and access packet (**Attachment 7(b)**).

## **12. Estimates of Annualized Burden Hours and Costs**

### **A. Estimate of annualized burden hours**

Fifty-nine health departments will serve as respondents for the **Adult HIV Confidential Case Report Form (Attachment 3a)** and report an estimated 789 responses (HIV and AIDS cases) each for a total of 46,551 responses. We estimate an average of 20 minutes per response for a total of 15,517 burden hours.

Pediatric cases will be reported by 59 health departments using the **Pediatric HIV Confidential Case Report Form (Attachment 3b)** and a subset of 47 health departments will also use the **Pediatric HIV Confidential Case Report Form (Attachment 3b)** for reporting of perinatal HIV exposures for a combined estimated 57 responses for a total of 3,363 annual responses. We estimate an average of 35 minutes per response for a total of 1,962 annual burden hours using the new consolidated PCRf (**Attachment 3b**).

The fifty-nine health departments will also conduct case report evaluations, reporting an estimated 85 responses each, for a total of 5,015 annual responses. We estimate an average 20 minutes per response for a total of 1,672 annual burden hours.

The annual burden hours for adult case reports decreased from the last revision from 16,795 hours to 15,517. Changes in reports are due to decreases in diagnoses and incidence and subsequent decreases in reports. Minor changes to the adult case reports described in detail in the changes document, will not result in changes to the estimated time per response for the adult HIV case reports or evaluations of HIV case reports. The burden estimate for the new pediatric HIV case report form reflects the inclusion of consolidated information from the previously approved Perinatal Exposure Report form together with the pediatric case report form. Specific changes are described in the accompanying changes document (**Attachment 10**). The number of responses and average time per response are revised to reflect the form changes and use for both perinatal exposure reporting and pediatric reporting.

The fifty-nine health departments also will process an average of 2,519 case report updates involving non-electronic methods each, totaling 148,621 responses annually. We estimate an average 2 minutes per response for a total of 4,954 burden hours. This is an increase from 4,628 burden hours to 4,954. This increase is due to an estimated

increase in the number of responses (from 138,827 to 148,621) to account for increased number of updates for CD4 and viral load test results among persons living with HIV.

We estimate 10,130 responses for laboratory updates through electronic methods in the 59 reporting areas for total of 597,668 responses annually. We estimate an average of 0.5 minute per electronic response for a total burden of 4,981 hours.

The fifty-nine jurisdictions also conduct deduplication activities including both routine interstate deduplication activities (RIDR) and cumulative interstate deduplication activities (CIDR). We estimate 59 areas complete deduplication activities will report 3,032 responses per respondent for an estimated 178,888 annual responses. We estimate 10 minutes per response based on published analyses and feedback from health departments on time to resolve duplicates for a total of 29,815 total burden hours.

Various investigations are routinely conducted by health departments as part of funded surveillance activities. Burden for investigations reporting and evaluation accounts for burden associated with reporting of cluster and data-to-care investigation variables reported through the NHSS. We estimate 59 areas will transmit data on investigation activities including 929 responses per respondent for an estimated 54,811 annual responses. We estimate 1 minute per response for a total of 914 total burden hours.

Three cluster report forms are used to monitor progress on cluster response (**Attachments 3e, 3f, 3g**). We estimate 59 areas will report on the initial cluster report form, reporting on average 2.5 responses per respondent for an estimated 148 annual responses. We estimate 1 hour per response for a total of 148 burden hours for the initial cluster report form. We estimate 59 areas will report on the cluster follow-up form collecting 5.0 responses per respondent for an estimated 148 annual responses. We estimate 30 minutes per response for a total of 148 burden hours for the cluster follow-up form. We estimate 59 areas will report on the cluster close-out form, reporting on average 2.5 responses per respondent for an estimated 148 annual responses. We estimate 1 hour per response for a total of 148 burden hours for the cluster close-out report form.

Fifty-nine jurisdictions will report on the quality of HIV Surveillance data using process and outcome standards once a year using the Standards Evaluation Report (SER) form (see **Attachment 3 d**). The SER is used to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives. The information collected for the annual SER includes a brief set of questions about evaluation outcomes, the collection of laboratory data for HIV surveillance and security and confidentiality practices that minimizes

the reporting burden on health departments. CDC provides standard SAS programs that can be run on state and local surveillance databases to extract the needed evaluation data. Laboratory reporting questions are used to characterize the completeness and quality of data reported from laboratories in each jurisdiction. Information collected on the SER is essential for establishing the accuracy and reliability of the national HIV surveillance data. There is no change in the estimated burden for SER. We estimate 8 hours per response for the SER for a total burden of 472 hours.

The total estimated burden in hours for this ICR is 60,731.

#### Exhibit 12.A Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Health Departments	Adult HIV Case Report (ACRF) (att 3a,4a)	59	789	46551	20/60	15517
Health Departments	Perinatal Exposure and Pediatric HIV Case Report (PCRF) (att 3b,4b)	59	57	3363	35/60	1962
Health Departments	Case Report Evaluations (att 3a,b,c)	59	85	5015	20/60	1672
Health Departments	Case Report Updates (att 3a,b,c)	59	2519	148621	2/60	4954
Health Departments	Laboratory Updates (att 3a,b,c)	59	10130	597670	0.5/60	4981
Health Departments	Deduplication Activities (att 4c)	59	3032	178888	10/60	29815
Health Departments	Investigation Reporting and Evaluation (att 4 d,e)	59	929	54811	1/60	914

Health Departments	Initial Cluster Report Form (att 3e,4f)	59	2.5	148	1	148
Health Departments	Cluster Follow-up Form(att 3f,4f)	59	5	295	0.5	148
Health Departments	Cluster Close-out Form (att 3g,4f)	59	2.5	148	1	148
Health Departments	Annual Reporting: Standards Evaluation Report (SER) (att 3d)	59	1	59	8	472
<b>Total</b>						<b>60731</b>

#### B. Estimates of Annualized Cost

The estimated total cost to respondents is \$1,821,863. This is based on an estimated hourly wage of \$30/hr. for each health department. Since typically the data collection is a collaborative effort, we used an average of an estimated salary of one data entry person at \$18.00/hr. and one epidemiologist at \$42/hr. for an estimated \$30/hr. The salary estimates were based on U.S. Department of Labor estimated mean hourly rates in the United States in 2017 for one data entry person (data entry keyer) at \$17.28/hr. and one epidemiologist at \$41.70/hr. Note this estimated cost is subsumed in the cooperative agreement costs outlined in section 14 below and should not be considered as additional costs.

#### Exhibit 12.B Estimates of Annualized Burden Cost

Type of Respondent	Form Name	No. of Respondents	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Hourly Wage Rate	Total Burden Cost
Health Departments	Adult HIV Case Report (ACRF)(att 3a,4a)	59	46551	20/60	\$30	\$465,510
Health Department	Perinatal HIV	59	3363	35/60	\$30	\$58,853

nts	Exposure and Pediatric HIV Case Report (PCRF)(att 3b, 4b)					
Health Departments	Case Report Evaluations (att 3a, b, c)	59	5015	20/60	\$30	\$50,150
Health Departments	Case Report Updates (att 3a, b, c)	59	148621	2/60	\$30	\$148,621
Health Departments	Laboratory Updates (att 3a, b, c)	59	597670	0.5/60	\$30	\$149,418
Health Departments	Deduplication Activities (att 4c)	59	178888	10/60	\$30	\$894,440
Health Departments	Investigation Reporting and Evaluation (att 4 d, e)	59	54811	1/60	\$30	\$27,406
Health Departments	Initial Cluster Report Form (att 3e, 4f)	59	148	1	\$30	\$4,440
Health Departments	Cluster Follow-up Form (att 3f, 4f)	59	295	30/60	\$30	\$4,425
Health Departments	Cluster Close-out Form (att 3g, 4f)	59	148	1	\$30	\$4,440
Health Departments	Annual Reporting Standards Evaluation Report (SER) (att 3d)	59	59	8	\$30	\$14,160
Total						\$1,821,863

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs to the respondent resulting from the collection of the information, other than their time.

### 14. Annualized Cost to the Federal Government

Exhibit 14 A. Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
CDC Costs	Data Management Staff 2 Analysts: 1 @ \$124,863 1 @ \$123,769	\$248,632
	Printing	\$4,500
	Software development, deployment, and maintenance*	\$1,697,188
	HIV Surveillance Branch Intramural, Including Personnel	\$6,669,480
	Subtotal	\$8,619,800
Cooperative Agreements with States	HIV Surveillance**	\$57,423,703***
	Total	\$66,043,503

\* Note presented as average of FY22, FY23, FY24 costs.

\*\* Note that these costs support the existing infrastructure of HIV surveillance programs in health departments. This includes costs related to data collection, analysis as well as other program costs.

\*\*\*FY 2022 HIV surveillance activities program costs. Estimates include annualized costs for HIV surveillance in U.S. affiliated pacific islands.

### 15. Explanation for Program Changes or Adjustments

Data collection instruments, data elements and a listing of specific changes to instrument content are provided. (See **Attachments 3a,3b,3c,3d,3e,3f,3g and Attachment 10.**)



The total estimated burden in hours for this ICR is 60,731 approximately 2% higher than our previous burden estimate of 59,462 approved in 2020 (non-substantial changes approved September 22, 2020, December 13, 2021). The small increase in burden overall is due to the decrease in burden from the removal of HIV incidence data collection balanced by increases in burden for reporting of laboratory and case updates, deduplication activities, and case investigations due to increases in prevalence and anticipated increases in reporting of perinatal exposures.

Specifically, changes in this revision include: 1) Discontinuation of one information collection activity (HIV incidence surveillance). The previously approved incidence program activity was not implemented. Incidence estimation will be continuing using statistical model without the need for additional data collection; 2) Program-initiated modifications to approved forms (both ACRF and PCRF) that improve usability and consolidation of the PCRF and PHER forms which were combined to reduce redundancy across the forms and better reflect the information necessary to assess progress with perinatal HIV elimination efforts and to support HIV prevention activities; 3) Minor decreases in new adult case reports using the ACRF due to decreases in HIV diagnoses; 4) Increased burden for case and laboratory updates, deduplication activities and case investigations due to the increasing number of persons living with HIV for which additional laboratory and case information is reported and linkage to care activities may be conducted; in addition, adjustments to the estimate of laboratory updates to account for reporting of perinatal exposed children who subsequently had negative test results reported also contributed to the increase. Exhibit A.15-A provides an overview of all changes proposed in this Revision request.

#### Exhibit A.15-A. Overview of Changes

Form Name	Approved Burden Hours as of Septemer 2020	Burden Hours Requested in this Revision	Net Change in Burden Hours	Overview of Changes to Burden and Forms
Adult HIV Case Report (ACRF) (att 3a,3c,4a)	16,795	15,517	-1,278	<b>DECREASE</b> in burden due to revised estimated number of responses per respondent <sup>(1)</sup> ; <b>MODIFIED</b> content of the ACRF with no change in average burden time per response.
Pediatric HIV Case Report (PCRF) (att 3b,3c,4b)	59	1962	+1903	<b>INCREASE</b> in burden due to revised estimated number of responses per respondent that includes burden moved from PHER form together with pediatric case reports on this revised form <sup>(1)</sup> ;

				<b>MODIFIED</b> content of the PCRf to include Pediatric Exposure information from PHER Form. PHER form no longer used.
Perinatal HIV Exposure Reporting (PHER)	1,576	0	-1,576	<b>DISCONTINUED form. MODIFIED</b> PCRf form now includes burden of perinatal exposures reports;
Case Report Evaluations (att 3a,3b,3c)	1691	1672	-19	<b>INCREASE</b> in burden due to revised estimated number of responses per respondent; <sup>1</sup>
Case Report Updates (att 3a,3b,3c,4a,4b)	4628	4954	+326	<b>INCREASE</b> in burden due to revised estimated number of responses per respondent; <sup>1</sup>
Laboratory Updates (att 3a,3b,3c,4a,4b)	4627	4981	+354	<b>INCREASE</b> in burden due to the revised estimated number of responses per respondent; <sup>2</sup>
Deduplication Activities (att 4c)	26,953	29815	+2,862	<b>INCREASE</b> in burden due to the revised estimated number of responses per respondent; <sup>2</sup>
Investigation Reporting and Evaluation (att 4 d,e)	886	914	+28	<b>INCREASE</b> in burden due to the revised estimated number of responses per respondent; <sup>2</sup>
Initial Cluster Report Form (att 3e,4f)	148	148	0	<b>NO CHANGE</b> in burden;
Cluster Follow-up Form (att 3f,4f)	148	148	0	<b>NO CHANGE</b> in burden;
Cluster Close-out Form (att 3g,4f)	148	148	0	<b>NO CHANGE</b> in burden;
Annual Reporting: Standards Evaluation Report (SER) (att 3d)	472	472	0	<b>NO CHANGE</b> in burden;
	59,462	60,731	+1,269	<b>NET INCREASE IN TOTAL BURDEN</b>

(1) Reflects reduction in case reports (diagnoses) due to improvements in prevention

(2) Reflects increases in prevalence due to improvements in medical care for persons with HIV.

### Discontinued Information Collections

HIV incidence surveillance was not implemented and is being discontinued as a separate activity. HIV Incidence continues to be

estimated via statistical methods (i.e., incidence estimation using a CD4 Depletion model) by CDC, lifting the burden off the grantees.

#### New or Modified Information Collection and Processing Activities

We have discontinued the use of the PHER form but will continue data collection of perinatal exposures on a the modified PCRF form. The modified PCRF form includes both changes to key pediatric report variables as well as incorporation of previously approved and new variables for perinatal exposure reports. (See form changes description below and the summary of changes (Attachment 10.) for specific changes). We also revised the average time per response of the PCRF form to account for both reporting of perinatal exposure and pediatric case information and revised the number of responses in our burden calculation to account for an anticipated increased number of jurisdictions reporting perinatal exposure information using the revised PCRF form (i.e., 47 jurisdictions are expected to report perinatal exposure data on the revised PCRF compared to 16 jurisdictions reporting using the previously approved (now discontinued) PHER form).

Our calculations include a smaller number of adult and pediatric case reports that account for fewer people receiving HIV diagnoses. This reduction is likely attributed to improvements in prevention efforts. In addition, the burden calculations for case report and laboratory updates, deduplication activities, and investigation reporting and evaluation activities account for increases in the number of persons living with HIV due to successes in treatment (increasing prevalence) and subsequent increased reporting for those burden line items.

#### Form Changes

The form changes requested for this ICR include modifications to currently collected data elements on the Adult HIV Confidential Case Report Form (ACRF), the consolidation of information collected from two forms (the Perinatal HIV Exposure Reporting [PHER] form and the Pediatric HIV Confidential Case Report Form [PCRF]) to one form (the PCRF), and modifications to associated data system tables and variables as a result of the revisions. The requested changes for forms and variables have been developed with input of state and local HIV surveillance coordinators and the CSTE HIV subcommittee and surveillance partners. We are requesting to continue data collection using our currently approved data collection instruments through December 2022 and implementing the proposed form changes starting in January 2023.

The specific changes to the adult and pediatric case report forms are described in detail in the attached "Summary of Proposed Changes" provided in **Attachment 10**.

A revised version of the ACRF is provided in **Attachment 3(a)** and the revised PCRf is provided in **Attachment 3(b)**. These forms will replace Attachments 3(a), 3(b) of our previously approved ICR.

Some reformatting, reordering and minor changes to wording of instructions were made for clarity and consistency and to improve organization of both the ACRF and revised PCRf forms.

Changes made to both the ACRF and PCRf include addition of two variables to collect sexual orientation information, updated gender identity response options, addition of two new HIV test types to accommodate changes in testing technology, the addition of two new response options related to self-testing, the addition of three new HIV testing history variables to summarize self-testing activities (ACRF only) and formatting changes to improve usability of both forms. In the Patient History section, we updated the language to align with the Division of HIV Prevention terminology guide, which recommends the use of 'person who injects drugs' instead of 'injection drug user'.

The main changes to the PCRf include those related to critical perinatal exposure information that was consolidated across the PHER and PCRf to reduce redundancy across forms and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities. Combining the PCRf and PHER forms reduced the information collected from the two forms which will reduce burden of data collection and increase usability of the forms. In all, 10 variables in the PHER form will no longer be collected; 7 variables from the PHER form were combined with existing variables on the PCRf; 13 variables were moved from the PHER form to the new PCRf; 5 new variables were added to the PCRf including 4 related to breastfeeding/chestfeeding and premastication risk behaviors and one variable related to documentation of laboratory results in a person's labor and delivery record; response options for the existing delivery method variable was revised on the PCRf to align with current medical practices. Health departments will now use the one revised PCRf form to report perinatal exposures and pediatric case reports and the revised burden for both perinatal exposure reporting and pediatric case reporting is now combined and included under the PCRf form line. The number of respondents reporting pediatric case reports is 59 and a subset of those jurisdictions that have perinatal exposure reporting will also report some perinatal exposure information using the revised PCRf form and the PCRf burden estimate has been revised to account for this reporting. The time per response for the PCRf has been revised from 20 minutes to 35 minutes average per response to reflect these changes and increased reporting of perinatal exposure data elements.

Minor modifications to dates and time periods in the Standards Evaluation Report (SER) are requested to better align with needed

information to assess program performance the next report cycle in January 2023. (Attachment 3d)

## **16. Plans for Tabulation and Publication and Project Time Schedule**

Collected HIV data are analyzed and published annually in the HIV Surveillance Report with quarterly updates to selected tables and slide sets found at <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Typically, the surveillance report is completed and published approximately- 18 months after a diagnosis year. Cases reported to CDC by the end of December are used for the annual HIV surveillance report, Supplemental Reports, and the NCHHSTP AtlasPlus and summarized through the end of the previous calendar year. For example, HIV surveillance data for 2020 were finalized in December 2021 and the report were posted on the DHP web site and updated in the AtlasPlus at the end of second quarter 2022. Over the years, data dissemination has increased to provide prompt dissemination of current HIV morbidity trends and timely evidence for decision makers related to program planning, evaluation, and resource allocation. For example, in 2020, DHP began releasing *HIV Surveillance Data Tables* and updating the NCHHSTP Atlas for selected HIV indicators on a quarterly basis for more timely monitoring of the Ending the HIV Epidemic in the U.S. (EHE) initiative. These quarterly data are also published in the Department of [Health and Human Services America's HIV Epidemic Analysis Dashboard \(AHEAD.\)](#)

For the ongoing HIV surveillance data collection, the following adjusted annual time schedule is presented in Exhibit 16 A. This annual estimate is based on the experience of the previous five years of data collection, analyses, and publication. Note this is an ongoing data collection cycle. Data are collected continuously throughout the three-year OMB approval period.

The HIV data are also included in DHP publications and materials for training and education of health care providers, researchers, the public, and the media. Numerous publications have resulted and will continue to result from the data. Special analyses are periodically conducted to summarize key trends, identify priority populations, and assist in developing new prevention strategies. These analyses are often published in peer-reviewed scientific journals. CDC also has distributed SAS analysis programs for state and local health departments to make standard site-specific tables and figures for use in their epidemiologic profiles for HIV Prevention and Ryan White HIV/AIDS Program community planning. These tools improve use of HIV data at the state and local levels. DHP/CDC also responds to special data requests to assist other government agencies and organizations in their HIV prevention activities.

Exhibit 16.A Project Time Schedule for Each Annual Data Collection\*

Activity	Time Schedule
Complete/submit forms 1-12 months after OMB approval	1-12 months after OMB approval
Final data validation	13-14 months after OMB approval
Final data analysis	15-17 months after OMB approval
Final annual report publication	18-23 months after OMB approval
Dissemination of results in other formats (e.g., supplemental reports, peer review articles)	23-36 months after OMB approval

\*Note this is an annualized estimate; data are collected continuously throughout the three-year period.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

DHP/CDC is not seeking an exception to the required display of the expiration date for the forms.

—

**18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h) (1)-(10)**

There are no exceptions to the certification.

**National HIV Surveillance System (NHSS)**

**OMB # 0920-0573**

**Supporting Statement  
Part B**

**August 8, 2022**

**Contact Information**

**Project Officer: Patricia Sweeney, MPH  
HIV Surveillance Branch  
Division of HIV Prevention  
National Center for HIV, Viral Hepatitis, STD, and TB Prevention  
Centers for Disease Control and Prevention  
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## **B. Statistical Methods**

### **1. Respondent Universe and Sampling Methods**

The Division of HIV Prevention (DHP), CDC, provides funding through cooperative agreements to all U.S. States, the District of Columbia, and U.S. dependent areas to conduct surveillance for HIV. Surveillance data collections are supported in 59 areas (the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, the Commonwealth of the Northern Mariana Islands, and the Federated States of Micronesia) using standard HIV case report forms (Note: the Marshall Islands, and Federated State of Micronesia are in the process of establishing these systems). It is anticipated that all 59 jurisdictions will be fully implementing HIV surveillance over the next three years. HIV surveillance case reports are obtained through both active and passive methods and are reported from a variety of sources to state health departments who in turn report these cases to CDC. Cases are typically reported to state/local health departments by laboratories, physicians, hospitals, clinics, and other health care providers using standard adult and pediatric case report forms. Additionally, health departments also abstract medical records in hospitals and other health care facilities to complete HIV case reports.

No sampling methods will be used to select respondents. Absolute case count is preferred to sampling for the following reasons: (1) HIV is a reportable disease and, therefore, states routinely collect information on each reportable case, and data collected by the HIV surveillance system assist local areas by identifying populations that need immediate attention and trends that help focus valuable resources; (2) DHP's goal is to reduce the burden of HIV in the United States and an absolute case count provides the best information on disease burden; and (3) reported HIV cases (all stages) are used for funding allocations for prevention and care programs by CDC and other federal agencies, for example the Ryan White HIV/AIDS Program administered by Health Resources and Services Administration (HRSA) and the Department of Housing and Urban Development (HUD) Housing Opportunities for Persons with AIDS (HOPWA) program.



## **2. Procedures for the Collection of Information**

State, local, and territorial laws and regulations require the reporting of HIV to health departments and health departments voluntarily share HIV case information with Centers for Disease Control and Prevention (CDC) as part of nationally notifiable disease reporting. Persons with HIV meeting the CDC surveillance case definitions for HIV [all stages, including stage 3 (AIDS)] are reported to the system based on clinical and laboratory criteria. These definitions have been updated periodically to accommodate advances in diagnostic and therapeutic standards and to improve standardization and comparability of surveillance data regarding persons with HIV at all stages. The most recent HIV case definition, including staging of disease, was published in 2014 (<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>). The Council of State and Territorial Epidemiologists (CSTE) and health-care professionals provided valuable input through consultations and peer review, in compliance with the Office of Management and Budget requirements for the dissemination of influential scientific information.

The current case definition combines the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case accommodates multitest algorithms, criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Additionally, clinical (non-laboratory) criteria for defining a case in the absence of HIV laboratory tests results. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition published in 2014 (<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>).

State health departments compile reported information from laboratories and care providers and serve as respondents for this surveillance system. CDC Technical Guidance for HIV Surveillance Programs describes practices and standards for conducting surveillance activities. Health departments use CDC provided software the enhanced HIV/AIDS Reporting System (eHARS) to manage surveillance data and report data to CDC on a monthly basis via a Secure Access Management System (SAMS). Data include demographic and geographic information (e.g., sex, gender, sexual

orientation, race, ethnicity, and residence), laboratory and clinical indicators of HIV infection (all stages), and behavioral and other risk factors related to HIV transmission. Name and date of birth are collected and retained by state and local health departments but names are removed before data are sent to CDC.

There are no minimum sample size requirements. As a reportable disease all diagnosed cases should get reported making sampling unnecessary. However, the local health departments routinely monitor the efficiency and performance of their local system and the quality of data reported to CDC. Whereas CDC monitors the quality of data at the national level, providing feedback to reporting areas to use in the investigation of incomplete, inconsistent, and unusual data and provides guidance and tools for evaluating system performance. CDC annually assesses surveillance system performance using process and outcome standards outlined in the Technical Guidance for HIV Surveillance Programs.

The minimum performance standards and recent assessments for surveillance programs are described in the "Standards Evaluation Report (SER) Form [Attachment 3 (d)]". Data quality assessments are critical for monitoring, evaluating, and interpreting HIV surveillance data used to monitor the National HIV/AIDS prevention goals and estimate the impact of HIV at all levels, as well as for documenting the strengths and weakness of data for public consumption.

The minimum performance standards include completeness of case reporting ( $\geq 95\%$ ), timeliness of case reporting ( $\geq 90\%$  of cases reported within 6 months of diagnosis), accurate case counts (less than 2% duplicate case reports), completeness of risk information ( $\geq 80\%$ ), initial CD4 test result ( $\geq 85\%$ ) and initial viral load test result ( $\geq 85\%$ ), and data quality checks (passed by  $\geq 97\%$  of cases for a diagnosis year).

Programs will continue to report this information annually as part of the SER.

### **3. Methods to Maximize Response Rates and Deal with Nonresponse**

This section is not applicable to the HIV surveillance system because of Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) which authorizes public health collection of this information.

#### **4. Test of Procedures or Methods to be Undertaken**

No additional tests of procedures or methods are proposed for this ongoing surveillance activity. Data collection instruments and data elements have been in use, and for the next cycle have been thoroughly reviewed and revised in consultation with state and local health departments.

For estimating HIV incidence, statistical methods do not require any information in addition to laboratory test results that are collected routinely (the CD4+ test results after HIV diagnosis). The method in use by CDC for estimating HIV incidence is based on a well characterized and tested CD4+ depletion model [Time From Human Immunodeficiency Virus Seroconversion to Reaching CD4+ Cell Count Thresholds <200, <350, and <500 Cells/mm<sup>3</sup>: Assessment of Need Following Changes in Treatment Guidelines (<http://dx.doi.org/10.1093/cid/cir494>), Using CD4 Data to Estimate HIV Incidence, Prevalence, and Percent of Undiagnosed Infections in the United States (<https://www.ncbi.nlm.nih.gov/pubmed/27509244>), which uses the first CD4+ test result after HIV diagnosis to estimate the duration for which the person has been infected with HIV.

#### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

CDC has extensively collaborated with CSTE regarding the HIV surveillance case definitions and reported data elements. Outside (non-CDC) individuals or agencies are occasionally consulted on statistical aspects of the design, collection and/or analysis of HIV data depending upon the problem being addressed and most often takes form as a multi-disciplinary panel.

## Attachment 1: Summary of Proposed changes

Table 1. SER changes		
Form, Page, Section, Question/Field	Change Proposed	Reason for Change Proposed
SER Form Pages 1-9	All evaluation periods are updated to reflect the years assessed in the 2024 report. Examples: <ul style="list-style-type: none"> <li>- Number of perinatally HIV exposed infants for birth year 2022</li> <li>- Of the expected number of persons whose HIV infection was diagnosed during 2022, at least (<math>\geq</math>) 95% are reported in the local HIV surveillance system, assessed December 2023</li> </ul>	To ensure that jurisdictions are reporting on the correct evaluation periods.
SER Form Page 4. Section E. Cluster Detection and Response	Changed name of section from “E. Cluster Detection and Response” to “E. Cluster Detection”	The 2 questions in this section focus on the detection part of Cluster Detection and Response, so the Response portion was dropped from the section name.
SER Form Page 4. Section F. Submission of Required Outcome Standards with SAS Tables	Added the list of jurisdictions that are required to report on Cumulative Interstate Duplicate Review (CIDR) progress.	Some jurisdictions completed 100% of their CIDR list by December 2022, so do not need to submit the CIDR report with the 2024 SER. This change will help health departments identify if they are required to report.
SER Form Page 6. Section G. Submission of Required Outcome Standards without SAS Tables	Changed section name from “G. Submission of Required Outcome Standards without SAS Tables” to “I. Cluster Response Performance Measures” and moved to the last section of the form, so that it is now section I.	The section name was changed to better describe the contents of the section. It was moved to the end of the form to separate it from the sections that assess surveillance activities as opposed to cluster response activities.
SER Form Page 5. Section F. Submission of Required Outcome Standards with SAS Tables	Moved the viral suppression in cluster members standard to Section I. Cluster Response Performance Measures.	The viral suppression in cluster members standard assesses effectiveness of response instead of surveillance activities. Therefore, this standard was moved to the appropriate section for cluster response measures.

**National HIV Surveillance System (NHSS)**

Attachment 2(a)

60 Day Federal Register Notice

increase of 6,312,230 annual responses (n=6,325,980) compared to that approved in 2019 (n=13,750). CDC also estimates the total annualized time burden is 5,592,688 hours, which is an increase of 5,591,150 hours compared to the previously approved 1,538 hours.

This increase in annual time burden is based largely on more accurate estimation of the number of respondents, the number of responses, and adding the 12-month recordkeeping burden for both AGE surveillance records and for maintenance and

sanitation records; this recordkeeping burden was not accurately accounted for in the prior ICR. There are no other costs to the respondents other than their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Cruise ship medical staff or other designated personnel.	AGE Illness Report 24 hours before arrival (web).	132	30	3/60
	AGE Illness Report 24 hours before arrival (phone/email/fax).	168	30	3/60
	AGE Illness Report 4 hours before arrival (web).	106	30	3/60
	AGE Illness Report 4 hours before arrival (phone/email/fax).	134	30	3/60
	Special Reports exceeding 2%–3% AGE Threshold (web/phone/email/fax).	180	4	3/60
	Daily Reports of AGE Logs .....	180	12	3/60
	Recordkeeping of AGE Surveillance Records	300	1	8,760
Cruise ship crew .....	72-hour Food/Activity History Template (AGE cases).	575	30	10/60
	Three-day Pre-embarkation AGE Illness Assessment (all crew members).	197,640	30	3/60
	Interviews to Determine AGE Status (initial, 24-hr, 48-hr)(asymptomatic cabin mates and immediate contacts of symptomatic crew).	2,875	90	5/60
	Last Symptom Check and Return to Work Clearance (food and nonfood employees).	575	30	3/60
Cruise ship passengers .....	72-hour Food/Activity History Template (AGE cases).	2,795	30	10/60
Cruise ship engineering staff or other designated personnel.	Recordkeeping of Engineering and Sanitation Records.	300	1	8,760

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

[FR Doc. 2022–06911 Filed 3–31–22; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60-Day–22–0573; Docket No. CDC–2022–0041]

### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of

its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on an information collection project titled National HIV Surveillance System (NHSS). The NHSS is designed to collect information on cases of human immunodeficiency virus (HIV) and indicators of HIV disease and HIV disease progression including AIDS. Data is used to monitor the extent and characteristics of the HIV burden in the United States.

**DATES:** CDC must receive written comments on or before May 31, 2022.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2022–0041 by either of the following methods:

• **Federal eRulemaking Portal:** *Regulations.gov.* Follow the instructions for submitting comments.

• **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *regulations.gov*.

**Please note:** Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS

H21–8, Atlanta, Georgia 30329; phone: 404–639–7118; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses; and
5. Assess information collection costs.

#### Proposed Project

National HIV Surveillance System (NHSS) (OMB Control No. 0920–0573, Exp. 11/30/2022)—Revision—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

CDC is authorized under Sections 304 and 306 of the Public Health Service Act (42 U.S.C. 242b and 242k) to collect information on cases of human immunodeficiency virus (HIV) and indicators of HIV disease and HIV disease progression, including AIDS. Data collected as part of the National HIV Surveillance System (NHSS) are the primary data used to monitor the extent

and characteristics of the HIV burden in the United States. HIV surveillance data are used to describe trends in HIV incidence, prevalence and characteristics of persons diagnosed with HIV infection and used widely at the federal, state, and local levels for planning and evaluating prevention programs and health-care services, allocating funding for prevention and care, and monitoring progress toward achieving national prevention goals of the Ending the HIV Epidemic in the U.S. initiative.

NHSS data collection activities are currently supported through cooperative agreements with health departments under CDC funding Opportunity Announcements PS18–1802: Integrated HIV Surveillance and Prevention Programs for Health Departments and PS20–2010 Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States. The activities funded under these announcements promote and support improving health outcomes for persons living with HIV through achieving and sustaining viral suppression, and reducing health-related disparities by using quality, timely, and complete surveillance, and program data to guide HIV prevention efforts toward reducing new HIV infections and ending the HIV epidemic in the United States.

The Division of HIV Prevention (DHP), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC in collaboration with health departments in the states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data reported across the spectrum of HIV disease stages from HIV diagnosis to death. The systematic data collection provides the essential data used to calculate population-based HIV incidence estimates, describe the geographic distribution of disease, monitor HIV transmission and drug resistance patterns and genetic diversity of HIV among infected persons, detect and respond to HIV clusters of recent and rapid transmission, and monitor perinatal exposures. NHSS data are also used locally to identify persons with HIV who are not in medical care and linking them to care and needed services. NHSS data continue to be collected, maintained, and reported using standard case definitions, report forms and software. The system is periodically updated as needed to keep pace with changes in testing technology and advances in HIV care and treatment, as well as changing prevention program monitoring and evaluation needs.

The revisions requested in this package include program-initiated modifications to currently collected data elements and forms including changes to the Adult Case Report Form (ACRF), the Pediatric Case Report Form (PCRF) and the Perinatal HIV Exposure Reporting (PHER) form. We request approval to continue data collection using our currently approved data collection instruments through December 2022 and implement the proposed form changes starting in January 2023. Changes made to both the ACRF and PCRF include addition of two variables to collect sexual orientation information, updated gender identity response options, addition of two new HIV test types to accommodate changes in testing technology, addition of two new response options related to self-testing, addition of three new HIV testing history variables to summarize self-testing activities (ACRF only) and formatting changes to improve usability of both forms. The main changes to the PCRF include those related to critical perinatal exposure information that was consolidated across the PHER and PCRF to reduce redundancy across forms and include some new and revised data elements needed to assess progress with perinatal elimination efforts and support HIV prevention activities. Combining the PCRF and PHER forms reduced the total number of pages of information collected from two forms with eight total pages to one form with six pages which will reduce burden of data collection and increase usability of the forms. In all, 10 variables in the PHER form will no longer be collected; seven variables from the PHER form were combined with existing variables on the PCRF; 13 variables were moved from the PHER form to the new PCRF; five new variables were added to the PCRF including four related to breastfeeding/chestfeeding and premastication risk behaviors and one variable related to documentation of laboratory results in a person's labor and delivery record; response options for the existing delivery method variable was revised on the PCRF to align with current medical practices. Health departments will now use the one revised PCRF form to report perinatal exposures and pediatric case reports and the revised burden for both perinatal exposure reporting and pediatric case reporting is now combined and included under the PCRF form line. The number of respondents reporting pediatric case reports is 59 and a subset of those jurisdictions that have perinatal exposure reporting will also report some perinatal exposure

information using the revised PCRf form and the PCRf burden estimate has been revised to account for this reporting. The time per response for the PCRf has been revised from 20 minutes to 35 minutes on average per response to reflect these changes and increased reporting of perinatal exposure data elements. HIV Incidence data collection as anticipated in the previous revision was not implemented and is being discontinued as a separate activity. HIV incidence continues to be estimated by CDC via statistical methods. No other revisions to the other data collection forms for this ICR are proposed. Burden estimates have been updated to reflect the discontinuation of incidence data collection, discontinued use of the PHER form for perinatal exposure reporting, and revised PCRf which will be used for both perinatal exposure reporting and pediatric case reporting. In addition, the revised burden estimate includes small increases in burden for case and laboratory updates, deduplication activities and case investigations due to the increasing number of persons living with HIV for which additional laboratory and case information is reported and linkage to care activities are conducted. The burden estimates for case reports decreased slightly since the last OMB approval due to decreases in adult and pediatric HIV diagnoses reported.

CDC provides funding for 59 jurisdictions to provide adult and pediatric HIV case reports. Additional information on perinatal exposures is also reported in a subset of jurisdictions when reportable using the same pediatric case report form and used to monitor progress toward perinatal HIV elimination goals. Health department staff compile information from laboratories, physicians, hospitals, clinics, and other health care providers to complete the HIV adult and pediatric case reports. CDC estimates that approximately 789 adult HIV case

reports and 57 perinatal exposure and pediatric case reports are processed by each health department annually.

These data are recorded using standard case report forms either on paper or electronically and entered into the electronic reporting system. Updates to case reports are also entered into the reporting system by health departments as additional information may be received from laboratories, vital statistics, or additional providers. Evaluations are also conducted by health departments on a subset of case reports (e.g. re-abstraction, validation). CDC estimates that on average approximately 85 evaluations of case reports, 2,519 updates to case reports and 10,130 updates of electronic laboratory test data will be processed by each of the 59 health departments annually. In addition, all 59 health departments will conduct routine deduplication activities for new diagnoses and cumulative case reports. CDC estimates that health departments on average will follow-up on 3,032 reports as part of deduplication activities annually. Case report information compiled over time by health departments is then de-identified and forwarded to CDC on a monthly basis to become part of the national HIV surveillance database.

Additional information will be reported by health departments for monitoring and evaluation of health department investigations including activities identifying persons who are not in HIV medical care and linking them to HIV medical care (e.g., Data-to-Care activities) and other services and identifying and responding to clusters. CDC estimates health departments will on average process 929 responses related to investigation reporting and monitoring annually.

Clusters of HIV are groups of persons related by recent, rapid transmission, for which rapid response is needed in order to intervene to interrupt ongoing

transmission and prevent future HIV infections. Health departments may detect clusters through multiple means, including through routine analyses of Surveillance data and other data reported to the NHSS. Data on clusters of recent and rapid HIV transmission in the United States will be collected to monitor situations necessitating public health intervention, assess health department response, and evaluate outcomes of intervention activities. These summary data will be collected through quarterly cluster report forms that will be completed by health departments for clusters that they have identified and for which they are actively conducting response activities. Health departments with detected clusters will complete an initial cluster report form when a cluster is first identified, a cluster follow-up form for each quarter in which the cluster response remains active and a cluster close-out form when cluster response activities are closed or at annual intervals while a cluster response remains active. CDC estimates on average health departments will provide information for 2.5 cluster initial cluster reports, five Cluster Follow-up Form reports, and 2.5 Cluster Close-out Form reports annually.

The Standards Evaluation Report (SER) is used by CDC and Health Departments to improve data quality, interpretation, usefulness, and surveillance system efficiency, as well as to monitor progress toward meeting surveillance program objectives. The information collected for the SER includes a brief set of questions about evaluation outcomes and the collection of laboratory data that will be reported one time a year by each 59 health departments.

CDC requests OMB approval for an estimated 60,731 annual burden hours in this Revision. There are no costs to respondents other than their time to participate.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Health Departments .....	Adult HIV Case Report (ACRF) .....	59	789	20/60	15,517
Health Departments .....	Perinatal Exposure and Pediatric HIV Case Report (PCRf) .....	59	57	35/60	1,962
Health Departments .....	Case Report Evaluations .....	59	85	20/60	1,672
Health Departments .....	Case Report Updates .....	59	2,519	2/60	4,954
Health Departments .....	Laboratory Updates .....	59	10,130	0.5/60	4,981
Health Departments .....	Deduplication Activities .....	59	3,032	10/60	29,815
Health Departments .....	Investigation Reporting and Evaluation .....	59	929	1/60	914
Health Departments .....	Initial Cluster Report Form .....	59	2.5	1	148
Health Departments .....	Cluster Follow-up Form .....	59	5	0.5	148



## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Health Departments .....	Cluster Close-out Form .....	59	2.5	1	148
Health Departments .....	Annual Reporting: Standards Evaluation Report (SER).	59	1	8	472
Total .....	.....	.....	.....	.....	60,731

Jeffrey M. Zirger,

Lead, Information Collection Review Office,  
Office of Scientific Integrity, Office of Science,  
Centers for Disease Control and Prevention.

[FR Doc. 2022-06917 Filed 3-31-22; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-22-22DT; Docket No. CDC-2022-0040]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Baseline Survey of National Education and Awareness Social Marketing Campaign: Employer Efforts to Support the Mental Health of Health Workers. This project is designed to conduct an electronic survey with healthcare workers and healthcare employers to establish a baseline to measure intended campaign outcomes.

**DATES:** CDC must receive written comments on or before May 31, 2022.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2022-0040, by either of the following methods:

- *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

*Please note:* Submit all comments through the Federal eRulemaking portal ([www.regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

#### Proposed Project

Baseline Survey of National Education and Awareness Social Marketing Campaign: Employer Efforts to Support the Mental Health of Health Workers—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

NIOSH is requesting approval of a new data collection for a period of one year under the project titled Baseline Survey of National Education and Awareness Social Marketing Campaign: Employer Efforts to Support the Mental Health of Health Workers. As part of the COVID-19 American Rescue Plan of 2021 and in response to a Congressional mandate, NIOSH is taking an active stance to address mental health concerns, to include substance use disorders, among the more than 20 million workers in the nation's healthcare sector. NIOSH, the federal agency tasked with conducting research to contribute to reductions in occupational illnesses, injuries, and hazards, plans to conduct a national social marketing campaign to promote awareness and education of employers and health workers about mental health. By conducting a national social marketing campaign, NIOSH intends to reach both health employers and health workers with information about organizational programs, services, policies, and practices to support worker mental health and the

## **National HIV Surveillance System (NHSS)**

Attachment 3(c)

Data Elements for the National HIV Surveillance System (NHSS)

## Data Elements for the National HIV Surveillance System (NHSS)

### Data Elements for Adult HIV I Case Reports

*Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0573)*

### Data Elements for Pediatric HIV Case Reports

*Public reporting burden of this collection of information is estimated to average 35 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0573)*

### Data Elements for Investigation Reporting and Evaluation

*Public reporting burden of this collection of information is estimated to average 1 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0573)*

The data elements listed below include data elements for adult/adolescent case reports (ACRF), pediatric case reports (PCRF), HIV incidence surveillance information (no longer collected), laboratory test data, investigation reporting and evaluation information and supplemental data collected from other document types such as birth certificates (BC), and death certificates (DEATH\_DOC). Data are stored in tables in the enhanced HIV Reporting System (eHARS). Information in the table below reflects information in the version of eHARS currently in place, v4.12, along with proposed changes to be implemented in eHARS v4.13 in 2023. The column "Transfer to CDC" indicates whether or not the data collected in a variable are transmitted to CDC. The column "Required/Optional" indicates whether a variable is: (1) a program requirement for collection (Required); (2) optional for program collection (Optional), which may include variables that are CDC recommended for collection but collection is optional; (3) generated by the eHARS system from entered values of other variables and is optional to collect (Optional-System); (4) generated by the eHARS system (System); (5) retired

from collection in eHARS (Retired); (6) retained from the previous case surveillance system and is not collected in eHARS (Legacy HARS); or (7) retained from the previous incidence surveillance system and is not collected in eHARS (Legacy Incidence). Additional information for users can be found in the eHARS 4.12 Technical Reference Guide for variables in the current version of eHARS; additional information about proposed changes to be implemented in eHARS v4.13 can be found in the Summary of Proposed Changes document.

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>ADDRESS</b>	<b>A table that maintains information on a person's addresses and locations.</b>				
address_dt	The most recent date for which this address is active.	YYYYMMDD	YES	ACRF, PCRF	Required
address_seq	Used by the system as a sequence identifier for a person's addresses.		YES	All	System
address_type_cd	A code indicating the type of address, such as RES (residential) or RSA (residence at AIDS diagnosis).	BAD - Bad address COR - Correctional facility CUR - Current FOS - Foster home HML - Homeless POS - Postal RAD - Residence at death RBI - Residence at birth RES - Residential RHE - Residence at perinatal exposure RSR - Residence at pediatric seroreversion RSA - Residence at diagnosis of stage 3 HIV infection (AIDS) RSH - Residence at diagnosis of HIV infection SHL - Shelter TMP – Temporary MIL – Military OTH - Other	YES	All	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
address_original_type_cd	Additional field for address type information when the address_type_cd captures an address event type.	BAD - Bad address COR - Correctional facility FOS - Foster home HML - Homeless POS - Postal RES - Residential SHL - Shelter TMP - Temporary MIL - Military OTH - Other	YES	All	Required
census_block_group	An optional field indicating the census block group for the person's address.		NO	ACRF, PCRF	Optional
census_congressional_district	An optional field indicating the congressional district for the person's address.		NO	ACRF, PCRF	Optional
census_group	An optional field indicating the census group for the person's address.		NO	ACRF, PCRF	Optional
census_msa	An optional field indicating the census metropolitan statistical area (MSA) for the person's address.		NO	ACRF, PCRF	Optional
census_tract	An optional field indicating the census tract for the person's address.		NO	ACRF, PCRF	Optional
city_fips	The city FIPS code for a person's address. (5 digits)	FIPS_CITY (table) - 99999	YES	All	Required
city_name	The textual city name for the person's address from the FIPS table. If there is no match to the FIPS table, the text is stored as entered by the user and preceded by an asterisk.	FIPS_CITY (table), ZIP_CITY (table)	YES	All	Required
country_cd	The ISO country code for a person's address.	COUNTRY_CODE (table)	YES	All	Required
country_usd	The FIPS U.S. dependency country code for the person's address.	COUNTRY_CODE (table)	YES	All	Required
county_fips	The FIPS county code for a person's address.	FIPS_COUNTY (table) - 999	YES	All	Required
county_name	The county name for the person's address from the FIPS table. If there is no match to the FIPS table, the text is	FIPS_COUNTY (table), ZIP_CITY (table)	YES	All	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
	stored as entered by the user and preceded by an asterisk.				
doc_belongs_to	Indicates who the address data belong to: PERSON, MOTHER, or CHILD.	PERSON, MOTHER, CHILD	YES	All	System
document_uid	A unique identifier for a document.		YES	All	System
geographic_level	Geographic level to which the address was geocoded.	1=Street match 2=Zip code match 3=City and state match 4=No match	YES	All	Required
phone	The value indicating a person's telephone number.	9999999999	NO	All	Required
state_cd	The state postal code for a person's address.	STATE_CODES	YES	All	Required
street_address1	Primary description of a person's street address, such as number and street name.		NO	All	Required
street_address2	Secondary description of a person's street address, such as apartment, building, or unit and number.		NO	All	Required
zip_cd	The zip code associated with a person's address.	ZIP_CITY (table) - 99999	NO	All	Required
<b>ARV_PROPHYLAXIS</b>	<b>Maintains information on a person's antiretroviral drug and prophylaxis use.</b>				
document_uid	Identifies the document associated with each record stored on the table; document_uid is a unique value generated by eHARS to identify a document.		YES	ACRF, PCRF	System
drug_seq	Used by the system as a sequence identifier for each antiretroviral drug added to a document.		YES	ACRF, PCRF	System
obs_uid	An internal identifier for an observation.		YES	ACRF, PCRF	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
drug_cd	Identifier for an antiretroviral drug.	DRUG	YES	ACRF, PCRF	Optional
drug_rsn	Reason the person took the antiretroviral drug.	DRUG_RSN_CD	YES	ACRF, PCRF	Required
other_drug_rsn	Text entered to specify the reason the persons took the antiretroviral drug when a selection value is not available or appropriate.		YES	ACRF, PCRF	Required, if drug_rsn="OTH"
drug_start_dt	The date the person began taking the antiretroviral drug.	YYYYMMDD	YES	ACRF, PCRF	Required
drug_last_use_dt	The date the person last used the antiretroviral drug.	YYYYMMDD	YES	ACRF, PCRF	Required
other_drug_specify	Unlisted antiretroviral drug name.		YES	ACRF, PCRF	Optional
<b>BIRTH_DELIVERY</b>	<b>A table to capture final outcome of previous pregnancies of birthing person.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System
delivery_seq	Sequence number. Implement sequence number to way RISK and ADDRESS to handle all codes on PV.	0-999999	YES	PCRF, LEGACY_PEDIATRIC	System
csection_rsn_cd	A code to determine why the delivery was a C-section.	CESAREAN	YES	PCRF, LEGACY_PEDIATRIC	Optional
other_csection_rsnl	User entered detail regarding delivery.		YES	PCRF, LEGACY_PEDIATRIC	Optional
<b>BIRTH_HISTORY</b>	<b>A table that maintains information pertaining to the child's birth or the mother's prenatal care, labor, and delivery. This information is collected in the Birth History section of Pediatric Case Report Forms (PCRF) and Birth Certificate (BC) documents.</b>				
congenital_disorders	From PCRF, indicates the presence of birth defects.	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
congenital_disorders_cd	From PCRF and BC, birth defect codes.	01 - Anencephaly 02 - Meningomyelocele/Spina bifida 03 - Cyanotic congenital heart disease 04 - Congenital diaphragmatic hernia 05 - Omphalocele 06 - Gastroschisis 07 - Limb reduction defect (excluding congenital amputation and dwarfing syndromes) 08 - Cleft lip with or without cleft palate 09 - Cleft palate alone 10 - Down syndrome 11 - Suspected chromosomal disorder 12 - Down syndrome (karyotype confirmed) 13 - Suspected chromosomal disorder (karyotype confirmed) 14 - Down syndrome (karyotype pending) 15 - Suspected chromosomal disorder (karyotype pending) 16 - Hypospadias 17 - None of the anomalies listed above	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
Birth_history_avail	Birth history available	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
birth_place	From BC, place of birth, such as home or hospital	1 - Hospital 2 - Freestanding birthing center 3 - Home birth, Clinic/Doctor's office 9 - Unknown	YES	BC	Optional
birth_type	From PCRF and BC, the type of birth, such as single or twin.	1 - Single 2 - Twin 3 - >2 9 - Unknown	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
birth_wt	From PCRF and BC, the child's birth weight in grams.	NULL, MIN = 28, MAX = 9070	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
breastfed	From PCRF and BC: Was this child breastfed?	YES_NO_UNK	YES	BC	Optional
delivery_dt	Date when birthing person delivered infant(s).	YYYYMMDD	YES	PCRF, LEGACY_PEDIATRIC	Optional
delivery_method	From PCRF and BC, the method of delivery, such as vaginal or Cesarean.	DELIVERY, DELIVERY_BC	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
delivery_time	Military time when birthing person delivered infant(s).	HH:MM:SS	YES	PCRF, LEGACY_PEDIATRIC	Optional
document_uid	A unique identifier for the PCRF or BC.		YES	All	System
infant_transfer	From BC: Was the infant transferred to another facility?	YES_NO	YES	BC	Optional
neonatal_status	From PCRF, the child's neonatal status.	1 - Full Term 2 - Premature 9 - Unknown	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
neonatal_status_weeks	From PCRF and BC, the gestational age of the child at delivery.	01 - 98, 99(unknown), 00(none)	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
rupture_dt	Date when membrane rupture occurred.	YYYYMMDD	YES	PCRF, LEGACY_PEDIATRIC	Optional
rupture_time	Military time when membrane rupture occurred.	HH:MM:SS	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>BIRTHING_PERSON_HISTORY</b>	<b>A table that maintains information pertaining to the birthing person's prenatal care, labor, and delivery. This information is collected in the Birthing Person History section of Pediatric Case Report Forms (PCRF) documents.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System
first_onc_visit_dt	From BC, the date of birthing person's first prenatal care visit	YYYYMMDD	YES	BC	Optional
last_pnc_visit_dt	From BC, the date of the birthing person's last prenatal care visit	YYYYMMDD	YES	BC	Optional
last_normal_menses_dt	From BC, the date of the birthing person's last prenatal care visit.	YYYYMMDD	YES	BC	Optional
month_preg_pnc	From PCRF, the month of pregnancy that birthing person's prenatal care began.	01 - 10, 99(unknown), 00(none) 1-9 are stored with leading zero.	YES	PCRF, LEGACY_PEDIATRIC	Optional
num_pnc_visits	From PCRF and BC, the number of prenatal care visits.	01-98, 99(unknown), 00(none) 1-9 are stored with leading zero.	YES	PCRF, LEGACY_PEDIATRIC	Optional
preg_before	Has the birthing person been pregnant before.	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
num_prev_preg	Total number of previous pregnancies	1-30	YES	PCRF, LEGACY_PEDIATRIC	Optional
num_prev_live_births	Number of previous live births	1-30	YES	BC	Optional
bp_cd4_test	Test result (with a specimen collection date withing 6 weeks on or before delivery)	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional
Bp_first_post_dt	Date of birthing person's first HIV positive test result	YYMMDD	YES	ACRF, PCRF, LEGACY ACRF, LEGACY PCRF, DEATH, LAB	Optional
bp_vl_test	Test result (with a specimen collection date withing 6 weeks on or before delivery)	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional
<b>CALC_OBSERVATION</b>	<b>A table that maintains information on a person's calculated observations.</b>				
calc_obs_uid	A unique identifier for a calculated observation.	CALC_OBSERVATION_CODE (table)	YES	All	Refer to CALC_OBSERVATION_C ODE table for requirements for each variable
calc_obs_value	The calculated observation's value.		YES	All	Refer to CALC_OBSERVATION_C ODE table for valid data element values for each variable
document_uid	A unique identifier for a document.		YES	All	System
<b>CALC_OBSERVATION_CO DE</b>	<b>A table that maintains information calc_obs_value and associated descriptions.</b>				
1	HARS Legacy - AIDS category	1 - Definitive (pre-85) case 2 - Definitive (1985) case 3 - Definitive (1987) case 4 - Presumptive (1987) case	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		5 - Definitive (1993) case 6 - Presumptive (1993) case 7 - Immunologic (1993) case 8 - Undetermined case 9 - Non-case			
2	HARS Legacy - HIV category	1 - HIV Definitive 2 - HIV Presumptive 3 - HIV Indeterminate 4 - HIV Negative Definitive 5 - HIV Negative Presumptive 8 - Pending Confirmation 9 - HIV Unknown	YES	All	System
3	HARS Legacy - Date the first disease was diagnosed based on the 1993 expanded AIDS case definition	YES_NO	YES	All	System
4	HARS Legacy - Date the first disease was diagnosed based on the pre-1993 expanded AIDS case definition	YYYYMMDD	YES	All	System
5	HARS Legacy - Date of the first condition classifying as AIDS based on the current AIDS case definition	YYYYMMDD	YES	All	System
6	HARS Legacy - Date of the first condition classifying as AIDS based on the applicable AIDS case definition	YYYYMMDD	YES	All	System
7	HARS Legacy - Date of last negative HIV test result	YYYYMMDD	YES	All	System
8	HARS Legacy - Date a case was reported as HIV positive	YYYYMMDD	YES	All	System
9	HARS Legacy - Date a case was reported as AIDS category level 1	YYYYMMDD	YES	All	System
10	HARS Legacy - Date a case was reported as AIDS category level 2	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
11	HARS Legacy - Date a case was reported as AIDS category level 3	YYYYMMDD	YES	All	System
12	HARS Legacy - Date a case was reported as AIDS category level 4	YYYYMMDD	YES	All	System
13	HARS Legacy - Date a case was reported as AIDS category level 5	YYYYMMDD	YES	All	System
14	HARS Legacy - Date a case was reported as AIDS category level 6	YYYYMMDD	YES	All	System
15	HARS Legacy - Date a case was reported as AIDS category level 7	YYYYMMDD	YES	All	System
16	HARS Legacy - Date a case was reported as not infected with HIV	YYYYMMDD	YES	All	System
17	HARS Legacy - Date a case was reported as perinatal exposure	YYYYMMDD	YES	All	System
18	HARS Legacy - Date the death of a case was reported	YYYYMMDD	YES	All	System
19	HARS Legacy - Mode of transmission	01 - Male sexual contact with other male (MSM) 02 - Injection drug use (nonprescription) (IDU) 03 - Male sexual contact with other male and injection drug use (MSM & IDU) 04 - Adult received clotting factor for hemophilia/coagulation disorder 05 - Heterosexual contact 06 - Adult received transfusion of blood/blood components, transplant of organ/tissue, or artificial insemination 08 - Adult with other confirmed risk 09 - Adult with risk not reported/other	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		11 - Child received clotting factor for hemophilia/coagulation disorder 12 - Mother with, or at risk for, HIV infection 13 - Child received transfusion of blood/blood components or transplant of organ/tissue 14 - Child with other risk 18 - Child with other confirmed risk 19 - Child with risk not reported/other			
20	HARS Legacy - Class	A1 - Asymptomatic, CD4 count > 500 or percent > 29% A2 - Asymptomatic, CD4 count 200-499 or percent 14-28% A3 - Asymptomatic, CD4 count < 200 or percent < 14% A9 - Asymptomatic, unknown CD4 B1 - Symptomatic, CD4 count > 500 or percent > 29% B2 - Symptomatic, CD4 count 200-499 or percent 14-28% B3 - Symptomatic, CD4 count < 200 or percent < 14%	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		B9 - Symptomatic, unknown CD4 C1 - AIDS, CD4 count > 500 or percent > 29% C2 - AIDS, CD4 count 200- 499 or percent 14-28% C3 - AIDS, CD4 count < 200 or percent < 14% C9 - AIDS, unknown CD4 Unknown clinical category, X1 - CD4 count > 500 or percent > 29% X2 - Unknown clinical category, CD4 count 200- 499 or percent 14-28% X3 - Unknown clinical category, CD4 count < 200 or percent < 14% X9 - Unknown clinical category, unknown CD4			
21	HARS Legacy - Date of first positive HIV test result or doctor diagnosis of HIV	YYYYMMDD	YES	All	System
78	HARS Legacy - CD4 count < 400	YES_NO	YES	All	System
85	HARS Legacy - First positive HIV-1 EIA test result date	YYYYMMDD	YES	All	System
86	HARS Legacy - Last negative HIV-1 EIA test result date	YYYYMMDD	YES	All	System
87	HARS Legacy - Most recent HIV-1 EIA test result value	POS=Positive NEG=Negative	YES	All	System
89	HARS Legacy - Most recent HIV-1 EIA test result date		YES	All	System
90	HARS Legacy - Overall HIV-1 EIA test result value	POS=Positive NEG=Negative	YES	All	System
91	HARS Legacy - Overall HIV-1 EIA test result date	YYYYMMDD	YES	All	System
92	HARS Legacy - First positive HIV-1/2 combined test result date	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
93	HARS Legacy - Last negative HIV-1/2 combined test result date	YYYYMMDD	YES	All	System
94	HARS Legacy - Most recent HIV-1/2 combined test result value	POS=Positive NEG=Negative	YES	All	System
95	HARS Legacy - Most recent HIV-1/2 combined test result date	YYYYMMDD	YES	All	System
96	HARS Legacy - Overall HIV-1/2 combined test result value	POS=Positive NEG=Negative	YES	All	System
97	HARS Legacy - Overall HIV-1/2 combined test result date	YYYYMMDD	YES	All	System
98	HARS Legacy - First positive Western Blot/IFA test result date	YYYYMMDD	YES	All	System
99	HARS Legacy - Last negative Western Blot/IFA test result date	YYYYMMDD	YES	All	System
100	HARS Legacy - Most recent Western Blot/IFA test result value	POS_NEG_IND	YES	All	System
101	HARS Legacy - Most recent Western Blot/IFA test result date	YYYYMMDD	YES	All	System
102	HARS Legacy - Overall Western Blot/IFA test result value	POS_NEG_IND	YES	All	System
103	HARS Legacy - Overall Western Blot/IFA test result date	YYYYMMDD	YES	All	System
104	HARS Legacy - First positive Other HIV Antibody test result date	YYYYMMDD	YES	All	System
105	HARS Legacy - Last negative Other HIV Antibody test result date	YYYYMMDD	YES	All	System
106	HARS Legacy - Most recent Other HIV Antibody test result value	POS_NEG_IND	YES	All	System
107	HARS Legacy - Most recent Other HIV Antibody test result date	YYYYMMDD	YES	All	System
108	HARS Legacy - Overall Other HIV Antibody test result value	POS_NEG_IND	YES	All	System
109	HARS Legacy - Overall Other HIV Antibody test result date	YYYYMMDD	YES	All	System



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
110	HARS Legacy - First positive Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
111	HARS Legacy - Last negative Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
112	HARS Legacy - Most recent Detection/Antigen/Viral load test result value	POS_NEG_IND	YES	All	System
113	HARS Legacy - Most recent Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
114	HARS Legacy - Overall Detection/Antigen/Viral load test result value	POS_NEG_IND	YES	All	System
115	HARS Legacy - Overall Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
116	HARS Legacy - Most recent CD4 count value		YES	All	System
117	HARS Legacy - Most recent CD4 percent value		YES	All	System
118	HARS Legacy - Most recent CD4 test result date	YYYYMMDD	YES	All	System
119	HARS Legacy - Lowest count from all CD4 test result values		YES	All	System
120	HARS Legacy - Lowest CD4 count test result date	YYYYMMDD	YES	All	System
121	HARS Legacy - Lowest percent from all CD4 test result values		YES	All	System
122	HARS Legacy - Lowest CD4 percent test result date	YYYYMMDD	YES	All	System
123	HARS Legacy - First CD4 count < 200 value		YES	All	System
124	HARS Legacy - First CD4 percent < 14 value		YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
125	HARS Legacy - First CD4 count < 200 or percent < 14 date	YYYYMMDD	YES	All	System
216	HARS Legacy - Expanded mode of transmission	01 - Male sexual contact with other male (MSM) 02 - Injection drug use (nonprescription) (IDU) 03 - Male sexual contact with other male and injection drug use (MSM & IDU) 04 - Adult received clotting factor for hemophilia/coagulation disorder 05 - Heterosexual contact with injection drug user 06 - Heterosexual contact with bisexual man 07 - Heterosexual contact with person with hemophilia 08 - Born in an NIR country Heterosexual contact with person born in an NIR country 09 - Heterosexual contact with HIV-infected transfusion recipient 11 - Heterosexual contact with HIV-infected person 12 - Heterosexual contact with person at risk for HIV infection 13 - Adult received transfusion of blood/blood	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		components, transplant of organ/tissue, or artificial insemination 14 - Adult with risk not reported/other 15 - Child received clotting factor for hemophilia/coagulation disorder 16 - Mother injection drug use (nonprescription) (IDU) 17 - Mother had sex with male injection drug user 18 - Mother had sex with bisexual man 19 - Mother had sex with person with hemophilia 20 - Mother born in an NIR country 21 - Mother had sex with person born in an NIR country 22 - Mother had sex with HIV-infected transfusion recipient 23 - Mother had sex with HIV-infected man 24 - Mother received transfusion of blood/blood components, transplant of organ/tissue, or artificial insemination 25 - Mother has HIV infection 26 - Child received transfusion of blood/blood components or transplant of organ/tissue			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		27 - Child with risk not reported/other 28 - Child with other risk 88 - Child with other confirmed risk			
217	Old race	1 - White, not Hispanic 2 - Black, not Hispanic 3 - Hispanic 4 - Asian/Pacific Islander 5 - American Indian/Alaska Native 9 - Unknown	YES	All	System
218	Race	1 - Hispanic, All races 2 - Not Hispanic, American Indian/Alaska Native 3 - Not Hispanic, Asian 4 - Not Hispanic, Black 5 - Not Hispanic, Native Hawaiian/Pacific Islander 6 - Not Hispanic, White 7 - Not Hispanic, Legacy Asian/Pacific Islander 8 - Not Hispanic, Multi-race 9 - Unknown	YES	All	System
219	Earliest date the first document was entered into the system	YYYYMMDD	YES	All	System
220	Earliest date the first document was received at the health department	YYYYMMDD	YES	All	System
221	Transmission category	01 - Male sexual contact with other male (MSM) 02 - Injection drug use (nonprescription) (IDU) 03 - Male sexual contact with other male and	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		injection drug use (MSM+IDU) 04 - Adult received clotting factor for hemophilia/coagulation disorder 05 - Heterosexual contact 06 - Adult received transfusion of blood/blood components, transplant of organ/tissue, or artificial insemination 07 - Perinatal exposure with HIV infection first diagnosed at age 13 years or older 08 - Adult with other confirmed risk 09 - Adult with No Identified Risk (NIR) 10 - Adult with No Reported Risk (NRR) 11 - Child received clotting factor for hemophilia/coagulation disorder 12 - Perinatal exposure 13 - Child received transfusion of blood/blood components or transplant of organ/tissue 18 - Child with other confirmed risk 19 - Child with No Identified Risk (NIR) 20 - Child with No Reported Risk (NRR)			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		99 - Risk factors selected with no age at diagnosis			
222	Expanded transmission category	01-Adult male sexual contact with male (MSM) 02-Adult injection drug use (IDU) 03-Adult MSM & IDU 04-Adult received clotting factor 05-Adult heterosexual contact with IDU 06-Adult heterosexual contact with bisexual male 07-Adult heterosexual contact with person with hemophilia or coagulation disorder 10-Adult heterosexual contact with transfusion or transplant recipient with documented HIV infection 11-Adult heterosexual contact with person with documented HIV infection, risk factor not specified 13-Adult received transfusion or transplant 14-Adult undetermined transmission category 15-Child received clotting factor 16-Mother IDU 17-Mother had heterosexual contact with IDU	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		18-Mother had heterosexual contact with bisexual male 19-Mother had heterosexual contact with person with hemophilia or coagulation disorder 22-Mother had heterosexual contact with transfusion or transplant recipient with documented HIV infection 23-Mother had heterosexual contact with person with documented HIV infection, risk factor not specified 24-Mother received transfusion or transplant 25-Mother HIV positive 26-Child received transfusion or transplant 27-Child undetermined transmission category 28-Child other confirmed risk factor 88-Adult other confirmed risk factor 99-Adult and pediatric risk factors selected with no age at diagnosis  f			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
223	Exposure category	01 - MSM only 02 - IDU only 03 - Heterosexual contact only 04 - MSM & IDU 05 - IDU & Heterosexual contact 06 - MSM & Heterosexual contact 07 - MSM & IDU & Heterosexual contact 08 - Perinatal exposure 09 - Other 10 - No Identified Risk (NIR) 11 - No Reported Risk (NRR) 99-Adult and pediatric risk factors selected with no age at diagnosis	YES	All	System
224	Date of first positive HIV test result or doctor diagnosis of HIV	YYYYMMDD	YES	All	System
225	Type of first evidence of HIV infection (positive HIV test result or doctor diagnosis of HIV)	1 - Lab test 2 - Physician diagnosis	YES	All	System
226	First CD4 or viral load test result date after HIV diagnosis	YYYYMMDD	YES	All	System
227	Type of first test after HIV diagnosis (CD4 or viral load)	1 - CD4 2 - Viral load 3 - CD4 and Viral Load	YES	All	System
228	Most recent test result date	YYYYMMDD	YES	All	System
229	Most recent test type	1 - CD4 2 - Viral load	YES	All	System
230	Most recent test result value	LAB_RESULT_VALUE	YES	All	System
243	First detectable viral load test result date	YYYYMMDD	YES	All	System



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
244	First detectable viral load test result value (copies/ml)		YES	All	System
245	Most recent viral load test result value (copies/ml)		YES	All	System
246	Most recent viral load test result date	YYYYMMDD	YES	All	System
247	Most recent undetectable viral load test result date	YYYYMMDD	YES	All	System
252	The earliest date on which the immunologic criteria for stage 3 were met	YYYYMMDD	YES	All	System
253	First CD4 count test result < 350 value		YES	All	System
254	First CD4 count test result < 350 date	YYYYMMDD	YES	All	System
255	Most recent CD4 count test result value		YES	All	System
256	Most recent CD4 count test result date	YYYYMMDD	YES	All	System
257	Most recent CD4 percent test result value		YES	All	System
258	Most recent CD4 percent test result date	YYYYMMDD	YES	All	System
259	Most recent CD4 test result (count or percent) date	YYYYMMDD	YES	All	System
260	First CD4 test result value after HIV diagnosis		YES	All	System
261	First CD4 test result date after HIV diagnosis	YYYYMMDD	YES	All	System
262	Lowest CD4 count test result value		YES	All	System
263	Lowest CD4 count test result date	YYYYMMDD	YES	All	System
264	Lowest CD4 percent test result value		YES	All	System
265	Lowest CD4 percent test result date	YYYYMMDD	YES	All	System
266	First positive Qualitative RNA/DNA test result date	YYYYMMDD	YES	All	System
267	Most recent Qualitative RNA/DNA test result value		YES	All	System
268	Most recent Qualitative RNA/DNA test result date	YYYYMMDD	YES	All	System
269	Most recent negative Qualitative RNA/DNA Test Result date	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
270	First positive HIV antigen test result date	YYYYMMDD	YES	All	System
271	First positive HIV culture test result date	YYYYMMDD	YES	All	System
272	HIV case definition category	1 - HIV positive, definitive 2 - HIV positive, presumptive 3 - HIV indeterminate 4 - HIV negative, definitive 5 - HIV negative, presumptive 8 - Pending confirmation 9 - Unknown	YES	All	System
273	AIDS case definition category	7 - AIDS case defined by immunologic (CD4 count or percent) criteria 9 - Not an AIDS case A - AIDS case defined by clinical disease (OI) criteria	YES	All	System
274	Age at HIV diagnosis (years)	1-99	YES	All	System
275	Age at HIV diagnosis (months)	1-99	YES	All	System
276	Age at AIDS diagnosis (years)	1-99	YES	All	System
277	Age at AIDS diagnosis (months)	1-99	YES	All	System
278	Age at HIV disease diagnosis (years)	1-99	YES	All	System
279	Age at HIV disease diagnosis (months)	1-99	YES	All	System
281	Date of the earliest condition classifying the case as stage 3 HIV infection	YYYYMMDD	YES	All	System
282	The earliest date on which the clinical disease criterion (opportunistic illness [OI] diagnosis) for stage 3 HIV infection was met	YYYYMMDD	YES	All	System
285	HIV disease diagnosis date	YYYYMMDD	YES	All	System
287	Diagnostic status	1 - Adult HIV 2 - Adult AIDS 3 - Perinatal HIV exposure	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		4 - Pediatric HIV 5 - Pediatric AIDS 6 - Pediatric seroreverter 9 - Unknown			
288	Date reported as HIV positive	YYYYMMDD	YES	All	System
289	Date reported as not infected with HIV (seroreverters)	YYYYMMDD	YES	All	System
290	Date reported as perinatal exposure	YYYYMMDD	YES	All	System
291	Date reported as AIDS (non- immunologic)	YYYYMMDD	YES	All	System
292	Date reported as AIDS (immunologic)	YYYYMMDD	YES	All	System
293	Date reported as AIDS (earliest)	YYYYMMDD	YES	All	System
294	Date reported as HIV disease	YYYYMMDD	YES	All	System
295	Disease progression category (report date)	YYYYMMDD	YES	All	System
296	Disease progression category (diagnosis date)	YYYYMMDD	YES	All	System
297	Meets CDC case definition for HIV (not AIDS)	YES_NO	YES	All	System
298	Meets CDC case definition for AIDS	YES_NO	YES	All	System
299	Meets CDC case definition for HIV disease	YES_NO	YES	All	System
300	Meets CDC eligibility for HIV (not AIDS)	YES_NO	YES	All	System
301	Meets CDC eligibility for AIDS	YES_NO	YES	All	System
302	Meets CDC eligibility for HIV disease	YES_NO	YES	All	System
303	Age at death (years)	1-99	YES	All	System
304	Age at death (months)	1-99	YES	All	System
305	Date death reported	YYYYMMDD	YES	All	System
306	Type of first CD4 test after HIV diagnosis (count or percent)	RESULT_UNITS_CD4	YES	All	System
307	Meets CDC case definition for HIV perinatal exposure or pediatric seroreverter	YES_NO	YES	All	System
308	Meets CDC eligibility for HIV perinatal exposure or pediatric seroreverter	YES_NO	YES	All	System
309	Laboratory documented date of last negative before first positive HIV test result	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
310	Date of last negative before first positive HIV test result from testing history	YYYYMMDD	YES	All	System
312	Stage 0 HIV infection at diagnosis	A – Stage 0, <b>acute</b> infection at diagnosis B – Stage 0, <b>unknown if acute</b> at diagnosis N – Insufficient evidence for diagnosis	YES	All	System
313	Stage at diagnosis based only on CD4 and opportunistic illness (OI)	1 - Stage 1, CD4 cnt≥500 or CD4 pct≥26 2 - Stage 2, 200≤CD4 cnt≤499 or 14≤CD4 pct≤25 3 - Stage 3, OI or CD4 cnt<200 or CD4 pct <14 9 - Stage unknown	YES	All	System
314	Date of earliest use of antiretroviral medications for HIV treatment	YYYYMMDD	YES	All	System
315	Date of last use of antiretroviral medications for HIV treatment	YYYYMMDD	YES	All	System
316	Date of earliest use of antiretroviral medications for pre-exposure prophylaxis	YYYYMMDD	YES	All	System
317	Date of last use of antiretroviral medications for pre-exposure prophylaxis	YYYYMMDD	YES	All	System
318	Date of earliest use of antiretroviral medications for post-exposure prophylaxis	YYYYMMDD	YES	All	System
319	Date of last use of antiretroviral medications for post-exposure prophylaxis	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
320	Date of earliest use of antiretroviral medications for prevention of mother-to-child transmission	YYYYMMDD	YES	All	System
321	Date of last use of antiretroviral medications for prevention of mother-to-child transmission	YYYYMMDD	YES	All	System
322	Date of earliest use of antiretroviral medications for Hepatitis B treatment	YYYYMMDD	YES	All	System
323	Date of last use of antiretroviral medications for Hepatitis B	YYYYMMDD	YES	All	System
324	Date of earliest use of antiretroviral medications for other reasons	YYYYMMDD	YES	All	System
325	Date of last use of antiretroviral medications for other reasons	YYYYMMDD	YES	All	System
326	Date of earliest use of antiretroviral medications	YYYYMMDD	YES	All	System
327	Date of last use of antiretroviral medications	YYYYMMDD	YES	All	System
328	Did mother receive any antiretroviral medications prior to this pregnancy?	YES, NO_REF_UNK	YES	All	System
329	Date of mother's earliest use of antiretroviral medications prior to this pregnancy	YYYYMMDD	YES	All	System
330	Date of mother's last use of antiretroviral medications prior to this pregnancy	YYYYMMDD	YES	All	System
331	Did mother receive any antiretroviral medications during pregnancy?	YES, NO_REF_UNK	YES	All	System
332	Date of mother's earliest use of antiretroviral medications during pregnancy	YYYYMMDD	YES	All	System
333	Date of mother's last use of antiretroviral medications during pregnancy	YYYYMMDD	YES	All	System
334	Did mother receive any antiretroviral medications during labor/delivery?	YES, NO_REF_UNK	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
335	Date of mother's earliest use of antiretroviral medications during labor/delivery	YYYYMMDD	YES	All	System
336	Date of mother's last use of antiretroviral medications during labor/delivery	YYYYMMDD	YES	All	System
337	Ever transgender or additional gender identity	MF, FM, AD	YES	All	System
<b>CONSENT_QUESTIONNAIRE</b>	<b>A table that maintains information on a person's consent for STARHS.</b> <b>Note: All variables in this tables were not collected since 2005 but are stored in eHARS.</b>				
cconsent1	Did the person consent to participate in STARHS when approached the first time?	YES_NO_UNK	YES	LEGACY_CONSENT	Retired
cconsent2	Did the person consent to participate in STARHS when approached the second time?	YES_NO_UNK	YES	LEGACY_CONSENT	Retired
cconsentvisit1	The type of visit when the person was approached for STARHS consent the first time.	01 - Pre-test 02 - Post-test 03 - Other Follow-up	YES	LEGACY_CONSENT	Retired
cconsentvisit2	The type of visit when the person was approached for STARHS consent the second time.	01 - Pre-test 02 - Post-test 03 - Other Follow-up	YES	LEGACY_CONSENT	Retired
cdate1	Date of first approach for consent.	YYYYMMDD	YES	LEGACY_CONSENT	Retired
cdate2	Date of second approach for consent.	YYYYMMDD	YES	LEGACY_CONSENT	Retired
document_uid	A unique identifier for a document.		YES	LEGACY_CONSENT	System
<b>DEATH</b>	<b>A table that maintains information on a person's death.</b>				
autopsy	Was an autopsy performed?	YES_NO_UNK	YES	LEGACY_NDI, DEATH_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
city_fips	The FIPS code for the city where the person died.	FIPS_CITY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
city_name	The name of the city where the person died.	FIPS_CITY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
country_cd	The ISO code for the country where the person died.	COUNTRY_CODE (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
country_usd	The U.S. Dependency code where the person died.	COUNTRY_CODE (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
county_fips	The FIPS code for the county where the person died.	FIPS_COUNTY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
county_name	The name of the county where the person died.	FIPS_COUNTY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
document_uid	A unique identifier for the Death Document.		YES	ACRF, PCRF, DEATH_DOC, LEGACY_NDI, LEGACY_ADULT, LEGACY_PEDIATRIC	System
dod	The person's date of death.	YYYYMMDD	YES	ACRF, PCRF, DEATH_DOC, LEGACY_NDI, LEGACY_ADULT, LEGACY_PEDIATRIC	Required if person's vital status = Dead
place	The type of place where the person died, such as a residence or hospital.	1 - Hospital, inpatient 2 - Hospital, outpatient or emergency room 3 - Hospital, dead on arrival 4 - Nursing home or hospice 5 - Residence 6 - Jail/Adult detention center 7 - Juvenile detention center 8 - Group/Assisted living home	YES	DEATH_DOC, LEGACY_NDI,	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		9 - Homeless shelter 10 - Homeless, on the street 11 - Hospital, institution (HARS) 888 - Other 999 - Unknown			
state_cd	The postal code for the state where the person died.	STATE_CODES	YES	ACRF, PCRF, DEATH_DOC, LEGACY_NDI, LEGACY_ADULT, LEGACY_PEDIATRIC	Required if person's vital status = Dead
<b>DEATH_DX</b>	<b>A table that maintains information on a person's causes of death.</b>				
descr	A phrase or statement describing the cause of death.		YES	LEGACY_NDI, DEATH_DOC	Optional
document_uid	A unique identifier for the Death Document.		YES	LEGACY_NDI, DEATH_DOC	Optional
icd_cd	The ICD code assigned.	ICD9, ICD10	YES	LEGACY_NDI, DEATH_DOC	Optional
icd_cd_type	The type of ICD code assigned, either ICD 9 (represented by 9) or ICD 10 (represented by 10).	9 - ICD-9 10 - ICD-10	YES	LEGACY_NDI, DEATH_DOC	Optional
line	A system generated number for NCHS electronic data, the line number on the tape.	1-9	YES	LEGACY_NDI, DEATH_DOC	Optional
line_number	A number indicating the sequence of death causes (00 is first).	00-20	YES	LEGACY_NDI, DEATH_DOC	Optional
nature_of_injury	For NCHS electronic data, the nature of injury flag (1 represents nature of injury codes and 0 represents all other cause codes).	0,1	YES	LEGACY_NDI, DEATH_DOC	Optional
position	Corresponds to the position of the cause of death on each line of the death		YES	LEGACY_NDI, DEATH_DOC	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
	certificate (1 if the cause is the first one listed, 2 if the cause is the second one listed, and so forth).				
<b>DOCUMENT</b>	<b>A table that maintains information about a document (such as a case report form).</b>				
author	The person who completed the original form.		NO	All	Optional
author_phone	The phone number of the person who completed the original form.	7 or 10 digits	NO	All	Optional
complete_dt	Date the form or document was completed or populated with information. For example, when the chart abstraction was completed.	YYYYMMDD	YES	All	Required
document_number	A field indicating the number of the document. For example, the certificate number associated with a birth certificate.		NO	All	Optional
document_source_cd	The source code of the document, such as A01 for Inpatient Record or A02 for Outpatient Record.	A01.01-Inpatient Record/Acute Care Facility A01.01.01-Inpatient Record/Acute Care Facility/Infection Control Practitioner A01.01.02-Inpatient Record/Acute Care Facility/Obstetrics and Gynecology A01.01.02.01-Inpatient Record/Acute Care Facility/Obstetrics and Gynecology/Prenatal Care A01.01.02.02-Inpatient Record/Acute Care Facility/Obstetrics and Gynecology/Labor and Delivery	YES	All	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A01.01.03-Inpatient Record/Acute Care Facility/Pediatric A01.01.04-Inpatient Record/Acute Care Facility/Birth A01.01.05-Inpatient Record/Acute Care Facility/All Other A01.02-Inpatient Record/Veteran's Administration Hospital A01.02.01-Inpatient Record/Veteran's Administration Hospital/Infection Control Practitioner A01.02.02-Inpatient Record/Veteran's Administration Hospital/All Other A01.03-Inpatient Record/Military Hospital A01.03.01-Inpatient Record/Military Hospital/Infection Control Practitioner A01.03.02-Inpatient Record/Military Hospital/Obstetrics and Gynecology A01.03.02.01-Inpatient Record/Military Hospital/Obstetrics and Gynecology/Prenatal Care			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A01.03.02.02-Inpatient Record/Military Hospital/Obstetrics and Gynecology Labor and Delivery A01.03.03-Inpatient Record/Military Hospital/Pediatric A01.03.04-Inpatient Record/Military Hospital/All Other A01.04-Inpatient Record/Long Term Care Facility A01.04.01-Inpatient Record/Long Term Care Facility/Nursing Home A01.04.02-Inpatient Record/Long Term Care Facility/Rehabilitation Center An inpatient facility specifically designed to help restore normal function (to the extent possible) in an A01.04.03-Inpatient Record/Long Term Care Facility/Drug Treatment Program A01.05-Inpatient Record/Hospice A02-Outpatient Record A02.01-Outpatient Record/HMO A02.01.01-Outpatient Record/HMO/Hospital- associated outpatient clinic			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.01.02-Outpatient Record/HMO/Non- Hospital associated outpatient clinic A02.02-Outpatient Record/VA Outpatient Clinic A02.03-Outpatient Record/Private Physician A02.03.01-Outpatient Record/Private Physician/Hospital- associated outpatient clinic A02.03.02-Outpatient Record/Private Physician/Non-Hospital associated outpatient clinic A02.04-Outpatient Record/Adult HIV Clinic A02.04.01-Outpatient Record/Adult HIV Clinic/Hospital-associated outpatient clinic A02.04.02-Outpatient Record/Adult HIV Clinic/Non-Hospital associated outpatient clinic A02.05-Outpatient Record/Infectious Disease Clinic A02.05.01-Outpatient Record/Infectious Disease Clinic/Hospital- associated outpatient clinic A02.05.02-Outpatient Record/Infectious Disease			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		Clinic/Non-Hospital associated outpatient clinic A02.06-Outpatient Record/County Health Dept. Clinic A02.07-Outpatient Record/Maternal HIV Clinic A02.07.01-Outpatient Record/Maternal HIV Clinic/Hospital-associated outpatient clinic A02.07.02-Outpatient Record/Maternal HIV Clinic/Non-Hospital associated outpatient clinic A02.08-Outpatient Record/Prenatal Clinic A02.08.01-Outpatient Record/Prenatal Clinic/Hospital-associated outpatient clinic A02.08.02-Outpatient Record/Prenatal Clinic/Non-Hospital associated outpatient clinic A02.09-Outpatient Record/Pediatric HIV Clinic A02.09.01-Outpatient Record/Pediatric HIV Clinic/Hospital-associated outpatient clinic A02.09.02-Outpatient Record/Pediatric HIV Clinic/Non-Hospital associated outpatient clinic A02.10-Outpatient Record/Obstetrics and Gynecology			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.10.01-Outpatient Record/Obstetrics and Gynecology/Hospital- associated outpatient clinic A02.10.02-Outpatient Record/Obstetrics and Gynecology/Non-Hospital associated outpatient clinic A02.11-Outpatient Record/Pediatric Clinic A02.11.01-Outpatient Record/Pediatric Clinic/Hospital-associated outpatient clinic A02.11.02-Outpatient Record/Pediatric Clinic/Non-Hospital associated outpatient clinic A02.12-Outpatient Record/TB Clinic A02.12.01-Outpatient Record/TB Clinic/Hospital- associated outpatient clinic A02.12.02-Outpatient Record/TB Clinic/Non- Hospital associated outpatient clinic A02.14-Outpatient Record/Indian Health Service Clinic A02.14.01-Outpatient Record/Indian Health Service Clinic/Hospital- associated outpatient clinic			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.14.02-Outpatient Record/Indian Health Service Clinic/Non- Hospital associated outpatient clinic A02.15-Outpatient Record/Early Intervention Nurse A02.15.01-Outpatient Record/Early Intervention Nurse/Hospital- associated outpatient clinic A02.15.02-Outpatient Record/Early Intervention Nurse/Non- Hospital associated outpatient clinic A02.16-Outpatient Record/Visiting Nurse Service A02.16.01-Outpatient Record/Visiting Nurse Service/Hospital- associated outpatient clinic A02.16.02-Outpatient Record/Visiting Nurse Service/Non-Hospital associated outpatient clinic A02.17-Outpatient Record/Hemophilia Treatment Center A02.17.01-Outpatient Record/Hemophilia Treatment Center/Hospital- associated outpatient clinic A02.17.02-Outpatient Record/Hemophilia Treatment Center/Non- Hospital associated outpatient clinic			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.18-Outpatient Record/Hospice A02.18.01-Outpatient Record/Hospice/Hospital- associated outpatient clinic A02.18.02-Outpatient Record/Hospice/Non- Hospital associated outpatient clinic A02.19-Outpatient Record/Drug Treatment Center A02.19.01-Outpatient Record/Drug Treatment Center/Hospital- associated outpatient clinic A02.19.02-Outpatient Record/Drug Treatment Center/Non- Hospital associated outpatient clinic A02.20-Outpatient Record/Rehabilitation Center A02.20.01-Outpatient Record/Rehabilitation Center/Hospital-associated outpatient clinic A02.20.02-Outpatient Record/Rehabilitation Center/Non-Hospital associated outpatient clinic A02.25-Outpatient Record/Other Clinic A02.25.01-Outpatient Record/Other			



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		Clinic/Hospital-associated outpatient clinic A02.25.02-Outpatient Record/Other Clinic/Non- Hospital associated outpatient clinic A03-Emergency Room A04-Screening, Diagnosis and Referral Agency A04.01-Screening, Diagnosis and Referral Agency/Blood Bank A04.02-Screening, Diagnosis and Referral Agency/Drug Treatment Clinic or Program A04.03-Screening, Diagnosis and Referral Agency/Family Planning Clinic A04.04-Screening, Diagnosis and Referral Agency/HIV Case Management Agency A04.05-Screening, Diagnosis and Referral Agency/HIV Counseling and Testing Site A04.06-Screening, Diagnosis and Referral Agency/Immigration A04.07-Screening, Diagnosis and Referral Agency/Insurance Report A04.08-Screening, Diagnosis and Referral Agency/Job Corps			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A04.09-Screening, Diagnosis and Referral Agency/Military A04.10-Screening, Diagnosis and Referral Agency/Partner Counseling and Referral Services A04.11-Screening, Diagnosis and Referral Agency/STD Clinic A04.12-Public health notes A05-Laboratory A05.01-Laboratory/Hospital A05.02-Laboratory/State A05.03-Laboratory/Private A05.03.01- Laboratory/Private/Referen ce A05.03.02- Laboratory/Private/Other A06-Other Database A06.01-Other Database/AIDS Drug Assistance Program (ADAP) A06.02-Other Database/ASD A06.03-Other Database/Birth Certificate A06.04-Other Database/Birth Defects Registry A06.05-Other Database/Cancer Registry A06.06-Other Database/Database			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		provided by coroner not associated with inpatient facility A06.07-Other Database/Death Certificate A06.08-Other Database/EHRAP A06.09-Other Database/EPS A06.10-Other Database/HARS A06.11-Other Database/Health department records A06.12-Other Database/Hepatitis Registry A06.13-Other Database/Hospital billing summary or discharge records A06.14-Other Database/HRSA HIV CARE A06.15-Other Database/Immunization registry A06.16-Other Database/Medicaid Records A06.17-Other Database/National Death Index (NDI) Search A06.18-Other Database/Out of State Reports A06.19-Other Database/Prison, Jail or Other Correctional Facility			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A06.20-Other Database/PSD A06.21-Other Database/State Disease Registry A06.22-Other Database/SHAS A06.23-Other Database/SHDC A06.24-Other Database/STD Registry A06.25-Other Database/Tuberculosis Registry A06.27-Other Database/Vital Statistics (State/Local) A06.28-Other Database/HARS NDI A06.29-Other Database/RIDR A06.29.01-Other Database/RIDR/CDC RIDR A06.29.02-Other Database/RIDR/CDC Soundex Check A06.29.03-Other Database/RIDR/Other State-to-State Communications A06.30-Other Database/SSDMF or SSDI A06.31-Other Database/Legacy TTH Pre- test			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A06.32-Other Database/Legacy TTH Post- test A06.33-Other Database/Legacy Consent A06.34-Other Database/MMP A06.34.01-Other Database/MMP/Medical Record Abstraction A06.34.02-Other Database/MMP/Patient Interview A06.35-Other Database/FIMR A06.35.01-Other Database/FIMR/Medical Record Abstraction A06.35.02-Other Database/FIMR/Patient Interview A06.36-Other Database/Internet Person/People Search A06.50-Other Database/Other A07-Other Facility Record A07.01-Other Facility Record/Prison, jail, or other correctional facility A07.02-Other Facility Record/Coroner not associated with inpatient facility A10-Other source A10.01-COPHI Investigation A10.02-Patient interview UNK-Unknown			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		SOURCE-No source defined			
document_type_cd	A code indicating the type of document, such as 001 for Adult Case Report Form or 005 for Birth Certificate.	000-document.personView 001- document.adultCaseReport Doc 002- document.pediatricReportD oc 003- document.harsAdultDoc 004-document.lab 005- document.birthCertificated oc 006- document.deathCertificate Doc 009document.harsPediatric Doc 010-Supplemental Risk Form 011-document.harsNdiDoc 012-document.tthDoc 013-document.consent  15 - document.starhs	YES	All	System
document_uid	A unique identifier for a document.		YES	All	System
ehars_uid	A unique identifier for a case or person.		YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
enter_by	The user ID of the person who entered the information into eHARS, auto-populated by the application.		NO	All	Optional
enter_dt	The system date when the document was entered into eHARS.	YYYYMMDD	YES	All	System
facility_uid	Indicates the facility completing the form.	FACILITY_CODE (table)	YES	ACRF, PCRF, LEGACY_CONSENT, LEGACY_TTH	Optional - System
initdocuid	If this document contains follow up information, this field captures the document UID of the report that initiated the investigation.		YES	All	Required if follow-up document
initinvest	Did this document initiate a follow-up investigation?	YES_NO_UNK	YES	All	Optional
modify_dt	The date the document was last modified.	YYYYMMDD	YES	All	Optional
notes	Notes or comments regarding the document.		NO	All	Optional
provider_uid	Indicates the provider completing the form.	PROVIDER_CODE (table)	NO	ACRF, PCRF, LEGACY_CONSENT, LEGACY_TTH	Optional - System
pv_categ	The Person View AIDS category at the time the document was entered into eHARS. <b>(Note: This field was retired from usage as of version 4.0)</b>		YES	All	System
pv_hcateg	The Person View HIV category at the time the document was entered into the system. <b>(Note: This field was retired from usage as of version 4.0)</b>		YES	All	System
receive_dt	The date the document was received at the health department.	YYYYMMDD	YES	All	Optional
rep_hlth_dept_cd	The health department reporting this information to the site. The code consists of the state abbreviation and either the three-digit FIPS county code (state + fips county code), or the five-digit FIPS place code (state + fips place code).	Two-character state abbreviation + three-digit FIPS county code or five-digit FIPS place code	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
rep_hlth_dept_name	The name of the reporting health department.		YES	All	Required
rpt_medium	An indication of the medium used to transport the information to the site, such as paper form, faxed or diskette, mailed.	1 - Paper form, field visit 2 - Paper form, mailed 3 - Paper form, faxed 4 - Telephone 5 - Electronic transfer, Internet 6 - Diskette, mailed	YES	All	Optional
ship_flag	A value indicating if the document/Person View needs to be transferred to state health department (satellite installations) or to CDC.	0-9999	YES	All	System
site_cd	A unique identifier representing the reporting site or location where eHARS is installed.	SITE_CODE	YES	All	System
status_flag	A value indicating the status of the document or Person View.	DOCUMENT_STATUS (non-pv documents), PERSON_VIEW_STATUS (pv documents)	YES	All	System
surv_method	A field indicating whether the report was obtained via active or passive surveillance.	A - Active F - Follow-up P - Passive R - Reabstraction U - Unknown	YES	All	Required
<b>FACILITY_CODE</b>	<b>A table that maintains information for selecting and identifying healthcare facilities.</b>				
city_fips	City FIPS code for the facility's address.	FIPS_CITY (table)	YES	N/A	Optional
city_name	City name associated with the facility's address.	FIPS_CITY (table)	YES	N/A	Optional
country_cd	ISO country code for the facility's address.	COUNTRY_CODE (table)	YES	N/A	Optional
country_usd	U.S. dependency code for the facility's address, if applicable.	COUNTRY_CODE (table)	YES	N/A	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
county_fips	County FIPS code for the facility's address.	FIPS_COUNTY (table)	YES	N/A	Optional
county_name	County name associated with the facility's address.	FIPS_COUNTY (table)	YES	N/A	Optional
email	The email address of the facility.		NO	N/A	Optional
facility_type_cd	A code indicating the type of healthcare facility.	F.OTH-Facility/Other F.UNK-Facility/Unknown F01-Inpatient Facility F01.01-Inpatient Facility/Hospital F01.04-Inpatient Facility/Long Term Care F01.50-Inpatient Facility/Drug Treatment F01.OTH-Inpatient Facility/Other F01.UNK-Inpatient Facility/Unknown F02-Outpatient Facility F02.01-Outpatient Facility/HMO Clinic F02.03-Outpatient Facility/Private Physician's Office F02.04-Outpatient Facility/Adult HIV Clinic F02.05-Outpatient Facility/Infectious Disease Clinic F02.09-Outpatient Facility/Pediatric HIV Specialty Clinic F02.10-Outpatient Facility/Obstetrics and Gynecology Clinic F02.11-Outpatient Facility/Pediatric Clinic	YES	N/A	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		F02.12-Outpatient Facility/TB Clinic F02.16-Outpatient Facility/Home Health Agency F02.17-Outpatient Facility/Hemophilia Treatment Center F02.18-Outpatient Facility/Hospice F02.19-Outpatient Facility/Drug Treatment Center F02.25-Outpatient Facility/Other Clinic F02.50-Outpatient Facility/ACTG Site F02.51-Outpatient Facility/Community Health Center F02.52-Outpatient Facility/Employee Health Clinic F02.53-Outpatient Facility/Health Department/Public Health Clinic F02.54-Outpatient Facility/Mobile Clinic F02.55-Outpatient Facility/Non-mobile Street Outreach F02.56-Outpatient Facility/PACTG Site			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		F02.57-Outpatient Facility/Primary Care Clinic, Not Specified F02.58-Outpatient Facility/School or University Clinic F02.OTH-Outpatient Facility/Other F02.UNK-Outpatient Facility/Unknown F03-Emergency Room F04-Screening, Diagnostic, Referral Agency (S,D,R) F04.01-(S,D,R) Blood Bank or Plasma Center F04.02-(S,D,R) Drug Treatment Center F04.03-(S,D,R) Family Planning Clinic F04.04-(S,D,R) HIV Case Management Agency F04.05-(S,D,R) HIV Counseling and Testing Site F04.07-(S,D,R) Insurance Screening F04.11-(S,D,R) STD Clinic F04.OTH-(S,D,R) Other F04.UNK-(S,D,R) Unknown F05-Laboratory F07-Other Specific Facility F07.01-Other Specific Facility/Correctional Facility F07.02-Other Specific Facility/Coroner or Medical Examiner			
facility_uid	A unique identifier for a healthcare facility.		YES	N/A	System
fax	The fax number of the facility.		NO	N/A	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
funding_cd	A code that indicates the type of HRSA funding a facility receives.	FUNDING_CD	YES	N/A	Optional
funding_flag	Does the facility receive HRSA funding?	YES_NO	YES	N/A	Optional
name1	Primary name of the facility.		YES	N/A	Optional
name2	Secondary or alternative name of the facility.		YES	N/A	Optional
phone	Phone number of the facility.		NO	N/A	Optional
setting_cd	A code identifying the setting of the facility, such as Federal, VA.	1-Public, unspecified 2-Federal, VA 3-Federal, IHS 4-Federal, military 5-Federal, corrections 6-Federal, other/unspecified 7-State 8-County/Parish 9-City/Town/Township 10-Private 999-Unknown	YES	N/A	Optional
ship_flag	A field used by the application to determine if the information for this facility needs to be transferred to CDC.	0 = Do not ship, 1 = Ship to CDC	NO	N/A	Optional
state_cd	State postal code of the facility's address.	STATE_CODES	YES	N/A	Optional
street_address1	Facility's primary street address.		NO	N/A	Optional
street_address2	Facility's secondary street address.		NO	N/A	Optional
zip_cd	Zip code for the facility's address.	ZIP_CITY (table)	YES	N/A	Optional
<b>FACILITY_EVENT</b>	<b>A table that maintains information pertaining to a person's events that involve a facility, such as facility at birth or facility at HIV diagnosis.</b>				
doc_belongs_to	Indicates if the facility event data (such as facility at HIV dx or facility at birth) belong to PERSON or CHILDn.	PERSON, MOTHER, CHILD	YES	All except DEATH_DOC and LAB_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
document_uid	A unique identifier for a document.		YES	All except DEATH_DOC and LAB_DOC	System
event_cd	A code that indicates the type of event that occurred.	01 - Facility of HIV diagnosis 02 - Facility of AIDS diagnosis 03 - Facility of perinatal exposure 05 - Hospital of birth 07 - Facility where child was transferred within 24 hours of delivery	YES	All except DEATH_DOC and LAB_DOC	Optional
facility_uid	The unique identifier of the facility associated with this event.	FACILITY_CODE (table)	YES	All except DEATH_DOC and LAB_DOC	Optional - System
provider_uid	The unique identifier of the provider associated with this event.	PROVIDER_CODE (table)	NO	All except DEATH_DOC and LAB_DOC	Optional - System
<b>ID</b>	<b>A table that maintains information on a person's identifiers.</b>				
doc_belongs_to	Indicates who the identifier belongs to: PERSON, MOTHER, or CHILD <i>n</i> .	PERSON, MOTHER, CHILD <i>n</i>	YES	ACRF, LEGACY_ADULT, PCRF, LEGACY_PEDIATRIC, BC	System
document_uid	A unique identifier for a document.		YES	All	System
id_cd	Code that indicates the type of identifier assigned to a person.	ID_CODE	YES	All	Refer to ID_CODE table for requirements for each variable
id_seq	Sequence identifier for a person's identification codes. A person can have multiple identification code types (id_cd_type) on the Person View document only.	1-99999999	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
id_value	The value of the person's identifier.		YES	All	Refer to ID_CODE table for valid data element values for each variable
<b>ID_CODE</b>	<b>A table that contains all distinct ID.id_cd values and associated descriptions, including any locally-defined ID types.</b> <b>*Required for the stateno associated with the state of report and the cityno associated with the applicable city of report.</b>				
001	FL STATENO		YES	All	Optional*
003	HRSA URN		NO	All	Optional
004	Medicaid Number		NO	All	Optional
005	GA STATENO		YES	All	Optional*
006	PA STATENO		YES	All	Optional*
007	Ryan White Number		NO	All	Optional
008	AIDS Drug Assistance Program (ADAP) Number		NO	All	Optional
009	STD*MIS Number		YES	All	Optional
010	Prison Number		NO	All	Optional
011	RVCT (TB) Number		YES	All	Optional
012	Social Security Number (SSN)		NO	All	Optional
013	Social Security Number Alias		NO	All	Optional
015	CA Non-named Code (reported)		NO	All	Optional
016	CA Non-named Code (verified)		NO	All	Optional
017	CT Coded Identifier (reported)		NO	All	Optional
019	DC Unique Id (reported)		NO	All	Optional
020	DC Unique Id (verified)		NO	All	Optional
021	DE Coded Identifier (reported)		NO	All	Optional
022	DE Coded Identifier (verified)		NO	All	Optional
023	HI Unnamed Test Code (reported)		NO	All	Optional
024	HI Unnamed Test code (verified)		NO	All	Optional
025	IL Patient Code Number (reported)		NO	All	Optional
026	IL Patient Code Number (verified)		NO	All	Optional
027	Philadelphia, PA Unique Code (reported)		NO	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
028	Philadelphia, PA Unique Code (verified)		NO	All	Optional
029	MA Coded Identifier (reported)		NO	All	Optional
030	MA Coded Identifier (verified)		NO	All	Optional
031	MD Unique Identifier (reported)		NO	All	Optional
032	MD Unique Identifier (verified)		NO	All	Optional
033	ME Coded Identifier (reported)		NO	All	Optional
034	ME Coded Identifier (verified)		NO	All	Optional
035	MT Coded Identifier (reported)		NO	All	Optional
036	MT Coded Identifier (verified)		NO	All	Optional
037	OR Coded Identifier (reported)		NO	All	Optional
038	OR Coded Identifier (verified)		NO	All	Optional
041	RI Coded Identifier (reported)		NO	All	Optional
042	RI Coded Identifier (verified)		NO	All	Optional
043	VT Non-named Code (reported)		NO	All	Optional
044	VT Non-named Code (verified)		NO	All	Optional
045	WA Non-named Coded Id (reported)		NO	All	Optional
046	WA Non-named Coded Id (verified)		NO	All	Optional
047	PATNO (HARS)		YES	All	Optional
048	HIVNO (HARS)		YES	All	Optional
049	Medical Record Number (MEDRECNO)		NO	All	Optional
050	TX STATENO		YES	All	Optional*
051	Houston, TX CITYNO		YES	All	Optional*
052	LA STATENO		YES	All	Optional*
053	WA STATENO		YES	All	Optional*
054	MI STATENO		YES	All	Optional*
055	AL STATENO		YES	All	Optional*
056	NJ STATENO		YES	All	Optional*
059	Counseling and Testing		NO	All	Optional
067	WA Non-named Code (generated)		NO	All	Optional
069	DC Unique Id (generated)		NO	All	Optional
070	DE Coded Identifier (generated)		NO	All	Optional
071	HI Unnamed Test Code (generated)		NO	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
072	IL Patient Code Number (generated)		NO	All	Optional
073	Philadelphia, PA Unique Code (generated)		NO	All	Optional
074	MA Coded Identifier (generated)		NO	All	Optional
075	MD Unique Identifier (generated)		NO	All	Optional
076	ME Coded Identifier (generated)		NO	All	Optional
077	MT Coded Identifier (generated)		NO	All	Optional
078	OR Coded Identifier (generated)		NO	All	Optional
079	PR Coded Identifier (retired)		NO	All	Optional
080	VT Non-named Code (generated)		NO	All	Optional
081	CA Non-named Code (generated)		NO	All	Optional
082	CT Coded Identifier (generated)		NO	All	Optional
083	RI Coded Identifier (generated)		NO	All	Optional
084	WA Non-named Code Alias (reported)		NO	All	Optional
086	CA Non-named Code Alias (reported)		NO	All	Optional
090	DC Unique Id Alias (reported)		NO	All	Optional
092	DE Coded Identifier Alias (reported)		NO	All	Optional
094	HI Unnamed Test Code Alias (reported)		NO	All	Optional
096	IL Patient Code Number Alias (reported)		NO	All	Optional
098	Philadelphia, PA Unique Code Alias (reported)		NO	All	Optional
100	MA Coded Identifier Alias (reported)		NO	All	Optional
102	MD Unique Identifier Alias (reported)		NO	All	Optional
104	ME Coded Identifier Alias (reported)		NO	All	Optional
106	MT Coded Identifier Alias (reported)		NO	All	Optional
108	OR Coded Identifier Alias (reported)		NO	All	Optional
112	RI Coded Identifier Alias (reported)		NO	All	Optional
114	VT Non-named Code Alias (reported)		NO	All	Optional
132	UCSF Patient Identifier		NO	All	Optional
133	Reporting Health Department Number (generic cityno)		YES	All	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
134	AK STATENO		YES	All	Optional*
135	AZ STATENO		YES	All	Optional*
136	AR STATENO		YES	All	Optional*
137	CA STATENO		YES	All	Optional*
138	CO STATENO		YES	All	Optional*
139	CT STATENO		YES	All	Optional*
140	DE STATENO		YES	All	Optional*
141	HI STATENO		YES	All	Optional*
142	ID STATENO		YES	All	Optional*
143	IL STATENO		YES	All	Optional*
144	IN STATENO		YES	All	Optional*
145	IA STATENO		YES	All	Optional*
146	KS STATENO		YES	All	Optional*
147	KY STATENO		YES	All	Optional*
148	ME STATENO		YES	All	Optional*
149	MD STATENO		YES	All	Optional*
150	MA STATENO		YES	All	Optional*
151	MN STATENO		YES	All	Optional*
152	MS STATENO		YES	All	Optional*
153	MO STATENO		YES	All	Optional*
154	MT STATENO		YES	All	Optional*
155	NE STATENO		YES	All	Optional*
156	UT STATENO		YES	All	Optional*
157	VT STATENO		YES	All	Optional*
158	VA STATENO		YES	All	Optional*
159	WV STATENO		YES	All	Optional*
160	WI STATENO		YES	All	Optional*
161	WY STATENO		YES	All	Optional*
162	NV STATENO		YES	All	Optional*
163	NH STATENO		YES	All	Optional*
164	NM STATENO		YES	All	Optional*
165	NY STATENO		YES	All	Optional*

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
166	NC STATENO		YES	All	Optional*
167	ND STATENO		YES	All	Optional*
168	OH STATENO		YES	All	Optional*
169	OK STATENO		YES	All	Optional*
170	OR STATENO		YES	All	Optional*
171	RI STATENO		YES	All	Optional*
172	SC STATENO		YES	All	Optional*
173	SD STATENO		YES	All	Optional*
174	TN STATENO		YES	All	Optional*
175	New York, NY CITYNO		YES	All	Optional*
176	American Samoa STATENO		YES	All	Optional*
177	Mariana Islands STATENO		YES	All	Optional*
178	DC STATENO		YES	All	Optional*
179	Guam STATENO		YES	All	Optional*
180	Puerto Rico STATENO		YES	All	Optional*
181	Virgin Islands STATENO		YES	All	Optional*
182	San Francisco, CA CITYNO		YES	All	Optional*
183	Los Angeles, CA CITYNO		YES	All	Optional*
184	Chicago, IL CITYNO		YES	All	Optional*
185	Philadelphia, PA CITYNO		YES	All	Optional*
186	PATNO (ASD)		YES	All	Optional
187	INS Number		NO	All	Optional
188	KY Unique Code Alias (Retired)		NO	All	Optional
189	Tracking ID		NO	All	Optional
190	Generic ID		NO	All	Optional
191	PEMS Client Unique Key		NO	All	Optional
192	PEMS Local Client Key		NO	All	Optional
193	PEMS Form ID		NO	All	Optional
195	Palau STATENO		YES	All	Optional
196	Marshall Islands STATENO		YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
197	MMP PARID		YES	All	Optional
198	FIMR ID		YES	All	Optional
199	Federated States of Micronesia STATENO		YES	All	Optional*
200	EvalWeb Client ID		NO	All	Optional
201	EvalWeb Form ID		YES	All	Optional
202	EvalWeb Partner Services Case Number		YES	All	Optional
203	Integrated Disease Surveillance System Person ID		No	All	Optional
204	Integrated Disease Surveillance System Event ID		No	All	Optional
<b>INVESTIGATION_CASE</b>	<b>A table that maintains the details of the HIV case investigation.</b>				
document_uid	A unique identifier for a document.		YES	ACRF	System
invest_case_seq	Sequence number to make the record unique.		YES	ACRF	System
invest_type_cd	Type of investigation	0 - Transmission Cluster 1 - Not in care	YES	ACRF	Required
invest_ident_method	How person was first identified as needing investigation.	01 - Health department HIV surveillance system (e.g., eHARS) 02 - Health department integrated data system 03 - Provider report 04 - Transmission cluster investigation 05 - Elevated viral load investigation 06 - Partner services investigation 07 - Medical Monitoring Project (MMP) 88 - Other	YES	ACRF	Required
invest_ident_dt	Date first identified as needing investigation	YYYYMMDD	YES	ACRF	Required
invest_incl	Included in investigation.	Y - Included in investigation N - Excluded from investigation	YES	ACRF	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
invest_start_dt	Date investigation opened.	YYYYMMDD	YES	ACRF	Required
invest_dispo	Investigation disposition.	1 - Deceased 2 - Resides out of jurisdiction 3 - In care 4 - Not in care 5 - Unable to determine	YES	ACRF	Required
invest_dispo_dt	Investigation disposition date.	YYYYMMDD	YES	ACRF	Required
invest_dispo_method	Basis of investigation disposition.	1 - Database/record search, only 2 - Patient contact/field investigation, only 3 - Database/record search and patient contact/field investigation	YES	ACRF	Required
int_dispo_dt	Intervention disposition date.	YYYYMMDD	YES	ACRF	Required
int_dispo	Intervention disposition.	1 —No linkage/re- engagement intervention initiated 2 - Linkage/re-engagement intervention declined by client 3 - Returned to care before linkage/re-engagement intervention was initiated 4 - Linkage/re-engagement intervention initiated, not successfully linked to/re- engaged in care 5 - Linked to/re-engaged in care, documented 6 - Linked to/re-engaged in care, client self-report, only 7 - Linkage/re-engagement status unknown	YES	ACRF	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>INVESTIGATION_CLUSTER</b>	<b>A table that maintains the details of molecular cluster investigation.</b>				
cluster_uid	Unique cluster ID number.	A-Z, 0-9, -, _, blank	YES	ACRF	Required
cluster_ident_method	Method of cluster identification.	01 - State/local molecular cluster analysis 02 - National molecular cluster analysis 03 - State/local time-space cluster analysis 04 - National time-space cluster analysis 05 - Provider notification 06 - Partner services notification 88 - Other	YES	ACRF	Required
document_uid	A unique identifier for a document.		YES	ACRF	System
invest_cluster_seq	Sequence number to make the record unique.		YES	ACRF	System
person_ident_met	How person was identified as part of this cluster.	1 - Through analysis/notification 2 - Through investigation	YES	ACRF	Required
person_ident_dt	Date person was identified as part of this cluster.	YYYYMMDD	YES	ACRF	Required
<b>LAB</b>	<b>A table that maintains information on a person's diagnostic tests and STARHS results.</b>				
accession_number	An identifier assigned by the lab to a specimen when received; acts as a tracking mechanism for the specimen.		NO	ACRF, PCRF, LAB_DOC	Optional
case_cd	For application use, a code associating a diagnostic test with the HIV/AIDS case definition algorithm.	LAB_TEST_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	System
clia_uid	The CLIA provider number of the laboratory that performed the test.	CLIA_CODE (table)	YES	ACRF, PCRF, LAB_DOC	Optional
comments	Notes or comments regarding a lab test entered by a user. These values are transferred to CDC.		YES	ACRF, PCRF, LAB_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
document_uid	A unique identifier for a document.		YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	System
facility_uid	The unique identifier of the facility that ordered the test.	FACILITY_CODE (table)	YES	ACRF, PCRF, LAB_DOC	Optional - System
lab_seq	Sequence identifier for a person's laboratory results.		YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	System
lab_test_cd	The eHARS defined codes to identify lab tests	LAB_TEST_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required
lab_test_type	The type of lab test.	LAB_TEST_TYPE <b>(As of version 4.0 the values below have been retired from usage.)</b> TYPE_OF_KIT TYPE_OF_KIT_STARHS TYPE_OF_KIT_VL	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional if the test is rapid
manufacturer	The manufacturer of the test (applicable to viral load tests only)	01-Bayer Diagnostics 02-Organon Teknika 03-Roche Molecular Systems Inc. 04-Abbott Laboratories 05-ABBOTT Molecular Inc. 06-Alere 07-Avioq Inc. 08-BioLife Plasma Services 09-bioLytical Laboratories Inc. 10-Bio-Rad Laboratories 11-Celera Diagnostics	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		12-Chembio Diagnostic Systems Inc. 13-Gen-Probe Inc. 14-Home Access Health Corp. 15-Maxim Biomedical Inc. 16-MedMira Laboratories Inc. 17-National Genetics Institute 18-OraSure Technologies 19-Ortho-Clinical Diagnostics Inc. 21-Sanochemia Pharmazeutika AG 22-Siemens Healthcare Diagnostics Inc. 23-Trinity Biotech 24-Becton Dickinson 25-Beckman Coulter 26-Cytognos 27-Guava Technologies 28-Partec 29-Invitrogen/Dynal biotech 30-PointCare technologies 31-Sysmex 32-i+MED Laboratories Co. Ltd. 33-Visible Genetics 34-Applied Biosystems 35-Virco 36-bioMerieux, Inc 37-Siemens Medical Solutions Diagnostics 38-Chiron Corporation 40-Streck 41-DiaSorin			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		42-Hologic 88-Other 99-Unknown			
provider_uid	The unique identifier of the provider who ordered the test.	PROVIDER_CODE (table)	NO	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional-System
receive_dt	The date the lab that performed the test received the specimen from either a healthcare provider or another laboratory.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result	The result value including the optical density for STARHS.	LAB_RESULT_VALUE (but depends upon the test)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required when entering a lab test
result_interpretation	An interpretation of the lab result. For viral load tests, values include: within range =, below range (limit) <, above range (limit) >. For STARHS tests the STARHS_RESULT values as found in LOOKUP_CODE table.	RESULT_INTERPRETATION - For viral load tests STARHS_RESULT - For STARHS tests Old HARS value "I" (indeterminate) [viewable only]	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result_range_lower	The lower boundary reference range or detection limit for viral load.	0-999.999,999	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result_range_upper	The upper boundary reference range or detection limit for viral load.	0-999.999,999	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result_rpt_dt	The date the test result was reported or processed at the lab.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
result_units	The reported units.	RESULT_UNITS_CD4, RESULT_UNITS	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required when entering a CD4 test
sample_dt	The date the specimen was collected.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required when entering a lab test
sample_id	A unique identifier used to distinguish samples; may be specimen number or ID.		NO	ACRF, PCRF, LAB_DOC	Optional
specimen	The type of specimen collected.	BLD - Blood OTH - Other SAL - Saliva UNK - Unknown URN - Urine	YES	ACRF, PCRF, LAB_DOC	Optional
sreason	The reason the STARHS specimen was not sent for testing.	1 - Quantity not sufficient 2 - Specimen never received at public lab 3 - Specimen broke in transit 4 - Other 5 - Not sufficient antibodies	YES	ACRF, PCRF, LAB_DOC	Optional
starhs_sample_id	If this is a confirmatory test aliquoted for STARHS, the STARHS specimen ID.		YES	ACRF, PCRF, LAB_DOC	If lab_test_cd=EC-023, EC-024, EC-025, EC-026, or EC-027 then this variable is REQUIRED
<b>LAB_ANALYTE</b>	<b>A table that contains the HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay lab test's analyte results.</b>				
document_uid	A unique identifier for a document.		YES	ACRF, PCRF, LAB_DOC	System
lab_seq	Sequence identifier for a person's laboratory results.		YES	ACRF, PCRF, LAB_DOC	System
lab_test_cd	The eHARS defined codes to identify lab tests	LAB_TEST_CODE (table)	YES	ACRF, PCRF, LAB_DOC	Required
result_interpretation	An interpretation of the lab result.	RESULT_INT_ANALYTE	YES	ACRF, PCRF, LAB_DOC	Required when entering a lab test
result	The result value.	0.00000-9999.99999, <, >, =	YES	ACRF, PCRF, LAB_DOC	Optional
result_units	The reported units	IDX	YES	ACRF, PCRF, LAB_DOC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>LAB_GENOTYPE</b>	<b>A table that contains the gene sequence from a person's genotype diagnostic test.</b>				
document_uid	A unique identifier for a document.		YES	ACRF, PCRF, LAB_DOC	System
genotype_sequence	The genotype sequence result from a genotype diagnostic test.	GENE_VALIDATION	YES	ACRF, PCRF, LAB_DOC	Required
lab_seq	Sequence identifier for a person's laboratory results.		YES	ACRF, PCRF, LAB_DOC	System
<b>OBSERVATION</b>	<b>A table that maintains information on a person's observations.</b>				
document_uid	An internal unique identifier for a document. For person-based local fields, the ehars_uid is stored in this field. For document-based local fields, the document_uid is stored in this field.		YES	All	System
obs_uid	An internal unique identifier for an observation.	OBSERVATION_CODE (table)	YES	All	Refer to OBSERVATION_CODE table for requirements for each variable
obs_value	The value for the observed object.		YES	All	Refer to OBSERVATION_CODE table for valid data element values for each variable
<b>OBSERVATION_CODE</b>	<b>A table that contains all distinct obs_value and associated descriptions.</b>				
1	Report status		YES	All	Optional
2	HARS Legacy - Laboratory name		YES	All	Legacy HARS
3	HARS Legacy - Other facility type at HIV diagnosis (specify)		YES	All	Legacy HARS
4	HARS Legacy - Has patient received a physical exam for this condition?	YES_NO_UNK	YES	All	Legacy HARS
5	HARS Legacy - Other facility type at perinatal exposure (specify)		YES	All	Legacy HARS
6	If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?	YES_NO_UNK	YES	All	Required if laboratory test not documented

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
7	Date patient was confirmed by a physician as HIV infected	YYYYMMDD	YES	All	Required if laboratory test not documented and physician diagnosis
8	Entered age at HIV diagnosis (years)		YES	All	Optional
9	Entered age at AIDS diagnosis (years)		YES	All	Optional
10	Clinical record reviewed	YES_NO	YES	All	Optional
11	Date patient was diagnosed as asymptomatic	YYYYMMDD	YES	All	Optional
12	Date patient was diagnosed as symptomatic	YYYYMMDD	YES	All	Optional
13	HARS Legacy - Other facility type at AIDS diagnosis (specify)		YES	All	Legacy HARS
14	Has patient been informed of his/her HIV infection?	YES_NO_UNK	YES	All	Optional
15	By whom patient's partners will be notified and counseled about their HIV exposure	PATIENT_NOTIFIER	YES	All	Optional
16	Is patient receiving or has patient been referred for medical services?	YES_NO_UNK	YES	All	Optional
17	Is patient receiving or has patient been referred for substance abuse treatment services?	YES_NO_NA_UNK	YES	All	Optional
18	HARS Legacy - Follow up date		YES	All	Legacy HARS
19	HARS Legacy - Follow up status of patient	1=Active follow-up 2=Moved from state 3=Provider out of state 4=Lost to follow-up 9=Unknown	YES	All	Legacy HARS
20	HARS Legacy - Laboratory ID number		YES	All	Legacy HARS
21	HARS Legacy - Did patient have heterosexual relations with a person born outside of the U.S.?	YES_NO_UNK	YES	All	Legacy HARS
22	HARS Legacy - Country of person with whom patient had heterosexual relations	See HARS country codes	YES	All	Legacy HARS
23	Patient is receiving or has been referred for OB-GYN services	YES_NO_UNK	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
24	Is patient currently pregnant?	YES_NO_UNK	YES	All	Required
25	Has patient delivered live-born infant?	YES_NO_UNK	YES	All	Optional
26	HARS Legacy - Has child's mother had sex with a man born outside of the U.S.?	YES_NO_UNK	YES	All	Legacy HARS
27	HARS Legacy - Is patient receiving HIV prophylactic therapy?	YES_NO_UNK	YES	All	Legacy HARS
28	HARS Legacy - Has patient been referred for treatment?	YES_NO_UNK	YES	All	Legacy HARS
29	HARS Legacy - Country of man with whom child's mother had sex	See HARS country codes	YES	All	Legacy HARS
31	HARS Legacy - Method of partner notification	1=Patient referred 2=Health department referred 8=Other provider	YES	All	Legacy HARS
32	HARS Legacy - Source of AIDS report	LEGACY_SOURCE	YES	All	Legacy HARS
33	HARS Legacy - Source of HIV report	LEGACY_SOURCE	YES	All	Legacy HARS
34	HARS Legacy - Source of AIDS report (specify)		YES	All	Legacy HARS
35	HARS Legacy - Source of HIV report (specify)		YES	All	Legacy HARS
39	Date of last medical evaluation	YYYYMMDD	YES	All	Optional
40	Date of initial evaluation for HIV infection	YYYYMMDD	YES	All	Optional
41	Was reason for initial HIV evaluation due to clinical signs/symptoms?	YES_NO_UNK	YES	All	Optional
42	Date of mother's first HIV positive test	YES_NO_UNK	YES	All	Optional
43	eHARS Retired — Was mother counseled about HIV testing during this pregnancy, labor, or delivery?	YES_NO_UNK	YES	All	Optional
44	eHARS Retired — If HIV tests were not positive or were not done, does this patient have an immunodeficiency that would disqualify him/her from AIDS case definition?	YES_NO_UNK	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
45	Is patient confirmed by a physician as not HIV infected?	YES_NO_UNK	YES	All	Optional
46	Date patient confirmed by physician as not HIV infected	YYYYMMDD	YES	All	Optional
47	Is child's birth history available?	YES_NO_UNK	YES	All	Optional
48	Entered diagnostic status at report	1 - Adult HIV 2 - Adult AIDS 3 - Perinatal HIV exposure 4 - Pediatric HIV 5 - Pediatric AIDS 6 - Pediatric seroreverter 9 - Unknown	YES	All	Optional
58	HARS Legacy - Mother's type of coagulation disorder	1=Hemophilia A 2=Hemophilia B 8=Other disorder	YES	All	Legacy HARS
74	HARS Legacy - Was mother diagnosed with HIV/AIDS?	YES_NO_UNK	YES	All	Legacy HARS
75	HARS Legacy - Was mother diagnosed with HIV/AIDS prior to child's birth?	YES_NO_UNK	YES	All	Legacy HARS
76	Has child received neonatal zidovudine?	YES_NO_UNK	YES	All	Retired
78	Has child received other neonatal anti-retroviral therapy?	YES_NO_UNK	YES	All	Retired
81	Has patient received anti-retroviral therapy?	YES_NO_UNK	YES	All	Retired
83	Has patient received PCP prophylaxis?	YES_NO_UNK	YES	All	Optional
84	Date PCP prophylaxis started	YYYYMMDD	YES	All	Optional
86	Is patient enrolled in government/other clinical trial?	PATIENT_ENROLLED_TRIAL	YES	All	Optional
87	Is patient enrolled at clinic?	PATIENT_ENROLLED_CLINIC	YES	All	Optional
88	HARS Legacy - Primary source of reimbursement for medical treatment	1=Medicaid 2=Private coverage 3=No coverage 4=Other public fund 7=Government program 9=Unknown	YES	All	Legacy HARS
89	Child's primary caretaker	1 - Biological parent(s) 2 - Other relative	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		3 - Foster/Adoptive parent, relative 4 - Foster/Adoptive parent, unrelated 7 - Social service agency 8 - Other (please specify in comments) 9 - Unknown			
90	HARS Legacy - For pediatric presumptive AIDS before 10/94, was lymphocyte count low (< 1000 ul)?	YES_NO_UNK	YES	All	Legacy HARS
91	HARS Legacy - For pediatric presumptive AIDS before 10/94, was CD4/CD8 ratio low (< 1000 ul)?	YES_NO_UNK	YES	All	Legacy HARS
92	HARS Legacy - For pediatric presumptive AIDS before 10/94, total serum immunoglobulins category	1=<1500 mg/dl 2=1500-2500 3=>2500 mg/dl 9=Unknown	YES	All	Legacy HARS
93	HARS Legacy - For pediatric presumptive AIDS before 10/94, highest total serum immunoglobulins value (mg/dl)		YES	All	Legacy HARS
94	HARS Legacy - For pediatric presumptive AIDS before 10/94, date of highest total serum immunoglobulins		YES	All	Legacy HARS
95	HARS Legacy - Was mother known to be uninfected after child's birth?	YES_NO_UNK	YES	All	Legacy HARS
96	HARS Legacy - Scheduled follow-up: TB update	range: 0-9, A-Z	YES	All	Legacy HARS
99	HARS Legacy - Scheduled follow-up: heterosexual case update	range: 0-9, A-Z	YES	All	Legacy HARS
100	HARS Legacy - Father's birthplace	1=US 7=US possession 8=Other 9=Unknown	YES	All	Legacy HARS

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
101	HARS Legacy - Father's country of birth	See HARS country codes	YES	All	Legacy HARS
102	HARS Legacy - Father's U.S. dependency of birth	See HARS US dependency codes	YES	All	Legacy HARS
114	Entered age at HIV diagnosis (months)		YES	All	Optional
115	Entered age at AIDS diagnosis (months)		YES	All	Optional
116	HARS Legacy - Clinical status assessed within one month of initial report	1=Asymptomatic 2=Symptomatic for HIV/AIDS	YES	All	Legacy HARS
118	HARS Legacy - NDI match category	1=Death not previously known 2=Death previously known; certificate identified by NDI 3=Death and certificate previously identified	YES	All	Legacy HARS
128	HARS Legacy - Scheduled follow-up: immunologic case update	range: 0-9, A-Z	YES	All	Legacy HARS
138	HARS Legacy - Physician name		YES	All	Legacy HARS
139	HARS Legacy - Patient name		YES	All	Legacy HARS
179	HARS Legacy - Comments from ARS		YES	All	Legacy HARS
180	HARS Legacy - Was this child referred?	1=Yes, by health dept. 2=Yes, by health care/provider 3=No, family refused 4=No 9=Unknown	YES	All	Legacy HARS
181	HARS Legacy - Comment line 1		YES	All	Legacy HARS
182	HARS Legacy - Comment line 2		YES	All	Legacy HARS
183	HARS Legacy - Comment line 3		YES	All	Legacy HARS
184	HARS Legacy - Comment line 4		YES	All	Legacy HARS
186	HARS Legacy - Date initial AIDS form completed	YYYYMMDD	YES	All	Legacy HARS
187	HARS Legacy - State GSA geographic code of current residence	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
189	HARS Legacy - Form (Adult of Pediatric)	A=Adult P=Pediatric	YES	All	Legacy HARS

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
190	HARS Legacy - Date initial HIV form completed	YYYYMMDD	YES	All	Legacy HARS
192	HARS Legacy - Date of HIV diagnosis reported at facility	YYYYMMDD	YES	All	Legacy HARS
194	HARS Legacy - Date of AIDS diagnosis reported at facility	YYYYMMDD	YES	All	Legacy HARS
196	HARS Legacy - State GSA geographic code of residence at HIV diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
197	HARS Legacy - State GSA geographic code of facility at HIV diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
198	HARS Legacy - Has child received IVIG therapy?	YES_NO_UNK	YES	All	Legacy HARS
199	HARS Legacy - Mother received blood products	YES_NO_UNK	YES	All	Legacy HARS
200	HARS Legacy - Date of perinatal HIV exposure reported at facility	YYYYMMDD	YES	All	Legacy HARS
202	HARS Legacy - State GSA geographic code of facility at perinatal HIV exposure	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
204	HARS Legacy - State GSA geographic code of residence at AIDS diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
205	HARS Legacy - Record shipment to CDC indicator	N=No Y, 2, ....=Yes	YES	All	Legacy HARS
206	HARS Legacy - State GSA geographic code of facility at AIDS diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
207	HARS Legacy - State GSA geographic code of reporting state	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
208	HARS Legacy - Record status	A - Active record B - Deleted record E - Fields in error F - Deleted with fields in error R – Required fields missing S – Deleted with reqd fields	YES	All	Legacy HARS



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		missing V - Pending verification W - Deleted before verified X – Reuse record in Database Z – ID number change			
210	HARS Legacy - Physician phone		YES	All	Legacy HARS
211	HARS Legacy - Reporting state	(FIPS_CITY.state_cd)	YES	All	Legacy HARS
212	HARS Legacy - Mother receive any other anti-retroviral medication during pregnancy (specify)		YES	All	Legacy HARS
220	Primary source of reimbursement for medical treatment at time of AIDS diagnosis	01 - CHAMPUS/TRICARE 02 - CHIP 03 - Medicaid 04 - Medicaid, pending 05 - Medicare 06 - Other public funding 07 - Private insurance, HMO 08 - Private insurance, PPO 09 - Private insurance, unspecified 10 - Self insured 11 - State funded, COBRA 12 - State funded, other 13 - State funded, unspecified 14 - VA 15 - No health insurance 88 - Other 99 - Unknown	YES	All	Optional
221	Primary source of reimbursement for medical treatment at time of HIV diagnosis	01 - CHAMPUS/TRICARE 02 - CHIP 03 - Medicaid 04 - Medicaid, pending 05 - Medicare 06 - Other public funding	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		07 - Private insurance, HMO 08 - Private insurance, PPO 09 - Private insurance, unspecified 10 - Self insured 11 - State funded, COBRA 12 - State funded, other 13 - State funded, unspecified 14 - VA 15 - No health insurance 88 - Other 99 - Unknown			
222	Did the documented laboratory test results meet approved alternate HIV testing algorithm criteria?	YES_NO_UNK	YES	All	Required if laboratory tests meet approved alternative algorithm
223	If YES, provide specimen collection date of earliest positive test for this algorithm	YYYYMMDD	YES	All	Required if laboratory tests meet approved alternative algorithm
224	Ever taken any ARVs?	YES_NO_UNK	YES	ACRF, PCRF	Required
225	Main source of antiretroviral (ARV) use information	1 - Provider Report 2 - Patient Interview 3 - Medical Record Review 4 - NHM&E 5 - Other	YES	ACRF	Required
227	Date patient reported information	YYYYMMDD	YES	ACRF	Required
229	Date of last use of PCP prophylaxis	YYYYMMDD	YES	ACRF, PCRF	Optional
230	eHARS Retired -Did mother receive zidovudine(ZDV,AZT) prior to this pregnancy?	YES_NO_UNK	YES	PCRF	Retired
231	eHARS Retired - Did mother receive zidovudine(ZDV,AZT) during pregnancy	YES_NO_REF_UNK	YES	PCRF	Retired

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
232	eHARS Retired -If yes, what week of pregnancy was zidovudine (ZDV, AZT) start)	01-52	YES	PCRF	Retired
233	eHARS Retired -Did mother receive any other Antiretroviral medication during pregnancy?	YES_NO_UNK	YES	PCRF	Retired
234	eHARS Retired -Did mother receive zidovudine(ZDV,AZT) during labor/delivery?	YES_NO_REF_UNK	YES	PCRF	Retired
235	eHARS Retired -Did mother receive any other Antiretroviral medication during labor/delivery	YES_NO_UNK	YES	PCRF	Retired
236	Did mother receive any ARVs prior to this pregnancy?	YES_NO_UNK	YES	PCRF	Optional
237	Did mother receive any ARVs during pregnancy?	YES_NO_UNK	YES	PCRF	Optional
238	Did mother receive any ARVs during labor/delivery?	YES_NO_UNK	YES	PCRF	Optional
239	Evidence of receipt of HIV medical care other than laboratory test result	1 – Yes, documented 2 – Yes, client self-report, only	YES	ACRF	Optional
240	Date of medical visit or prescription	YYYYMMDD	YES	ACRF	Optional
241	Suspect acute HIV infection	YES_NO_UNK	YES	ACRF	Optional
242	Clinical sign/symptom consistent with acute retroviral syndrome	YES_NO_UNK	YES	ACRF	Optional
243	Date of acute retroviral syndrome sign/symptom onset	YYYYMMDD	YES	ACRF	Optional
244	Other evidence suggestive of acute HIV infection	YES_NO_UNK	YES	ACRF	Optional
245	Date of other evidence	YYYYMMDD	YES	ACRF	Optional
246	Description of other evidence	[A-Z,0-9, special character]	YES	ACRF	Optional
247	eHARS Retired - 1. If information on the mother is not available, was the child adopted, or in foster care?	YES_NO_NA	YES	PCRF	Retired
248	eHARS Retired -2. Records Abstracted		YES	PCRF	Retired
249	eHARS Retired -3. Weeks' gestation at first prenatal care visit.		YES	PCRF	Retired

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
250	eHARS Retired - 19. Was mothers HIV serostatus noted in prenatal care, labor and delivery and child's birth records?	YHIVP_YHIVN_NO_RNA_UN K	YES	PCRF	Retired
251	eHARS Retired -12. Were ARV's prescribed for the mother during this pregnancy: gestational age		YES	PCRF	Retired
252	eHARS Retired -14.Did mother receive ARV's during labor and delivery?: time received, type of administration		YES	PCRF	Retired
253	eHARS Retired -20.Were antiretroviral drugs prescribed for the child?: time started, art completed, stop codes		YES	PCRF	Retired
254	eHARS Retired -15. Was mother referred for HIV care after delivery?	YES_NO_ND_RNA_UNK	YES	PCRF	Retired
255	eHARS Retired -16a. Indicate first CD4 result after discharge from hospital (up to 6 months after discharge)		YES	PCRF	Retired
256	eHARS Retired -16b. Indicate first viral load after discharge from hospital (up to 6 months after discharge)		YES	PCRF	Retired
257	eHARS Retired -17. Birth information available	BNH_RNA	YES	PCRF	Retired
258	eHARS Retired -17. Onset of labor	YES_NO hh:mm:ssss MM/DD/YYYY	YES	PCRF	Retired
259	eHARS Retired -17. Admission to labor and delivery	YES_NO hh:mm:ssss MM/DD/YYYY	YES	PCRF	Retired
260	eHARS Retired - 7. Sibling date of birth, HIV serostatus, State No, City No		YES	PCRF	Retired
261	eHARS Retired - 8. Was substance use during pregnancy noted in medical or social work records?		YES	PCRF	Retired
262	eHARS Retired - 8b. If substances used, were any injected? Specify injected substance(s).		YES	PCRF	Retired

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
263	eHARS Retired - 9. Was a toxicology screen done on the mother (either during pregnancy or at the time of delivery)?		YES	PCRF	Retired
264	eHARS Retired - 10. Was a toxicology screen done on the infant at birth?	YPR_YNR_NO_TSND	YES	PCRF	Retired
265	eHARS Retired - Was this child breastfed?	YES_NO	YES	PCRF	Retired
266	eHARS Retired - Maternal stateno		YES	PCRF	Retired
<b>OI</b>	<b>A table that maintains information on a person's opportunistic infections (diseases indicative of AIDS).</b>				
document_uid	A unique identifier for a document.		YES	All	System
dx	A code indicating if the diagnosis was presumptive or definitive.	DEF_PRE	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
dx_dt	The date the AIDS defining condition was diagnosed.	YYYYMMDD	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
oi_cd	A code indicating a person's AIDS defining conditions.	AD01 - Bacterial infection, multiple or recurrent (including Salmonella septicemia) AD02 - Candidiasis, bronchi, trachea, or lungs AD03 - Candidiasis, esophageal AD04 - Carcinoma, invasive cervical AD05 - Coccidioidomycosis, disseminated or extrapulmonary AD06 - Cryptococcosis, extrapulmonary AD07 - Cryptosporidiosis, chronic intestinal (>1 mo. duration) AD08 - Cytomegalovirus disease (other than in liver, spleen, or nodes)	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		AD09 - Cytomegalovirus retinitis (with loss of vision) AD10 - HIV encephalopathy AD11 - Herpes simplex: chronic ulcer(s) (>1 mo. duration) or bronchitis, pneumonitis, or esophagitis AD12 - Histoplasmosis, disseminated or extrapulmonary AD13 - Isosporiasis, chronic intestinal (> 1 mo. duration) AD14 - Kaposi's sarcoma AD15 - Lymphoid interstitial pneumonia and/or pulmonary lymphoid AD16 - Lymphoma, Burkitts (or equivalent term) AD17 - Lymphoma, immunoblastic (or equivalent term) AD18 - Lymphoma, primary in brain AD19 - Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary AD20 - M. tuberculosis, pulmonary AD21 - M. tuberculosis, disseminated or extrapulmonary AD22 - Mycobacterium, of other species or unidentified species,			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		disseminated or extrapulmonary AD23 - Pneumocystis carinii pneumonia AD24 - Pneumonia, recurrent, in 12 mo. period AD25 - Progressive multifocal leukoencephalopathy AD26 - Salmonella septicemia, recurrent AD27 - Toxoplasmosis of brain, onset at >1 mo. of age AD28 - Wasting syndrome due to HIV			
oi_seq	Sequence identifier for a person's AIDS defining conditions.	0-99,999,999	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	System
<b>OTHER_HEALTH_CONDI TIONS</b>	<b>A table that maintains the health conditions, other than HIV, of birthing person and infant during pregnancy, labor and delivery. This information is collected in the Birth History and Birthing Person History sections of Pediatric Case Report Forms (PCRF) documents.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System
condition_seq	Sequence number. Implement sequence number to way RISK and ADDRESS to handle all codes on PV.	0-999999	YES	PCRF, LEGACY_PEDIATRIC	System
condition_event_cd	Connects to the overall question or section to allow storage when data gathered for different questions for the same case.	CONDITION_EVENT_CD	YES	PCRF, LEGACY_PEDIATRIC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
condition_cd	Unique code for health condition	HEALTH_CONDITION_CD	YES	PCRF, LEGACY_PEDIATRIC	Optional
condition_value	Screening value or diagnosis value of other health condition.	YES_NO_UNK - only for new records, manual entry and ADI ND & RNA- valid for PHER converted data and will appear as greyed out options in manual entry drop-down box	YES	PCRF, LEGACY_PEDIATRIC	Optional
condition_dt	Date screening or performed or date condition diagnosed.	YYYYMMDD .	YES	PCRF, LEGACY_PEDIATRIC	Optional
doc_belongs_to	Indicates who the address data belong to: PERSON, MOTHER.	PERSON, MOTHER	YES	PCRF, LEGACY_PEDIATRIC PCRF, LEGACY_PEDIATRIC	System
<b>PERSON</b>	<b>A table that maintains demographic information about a person.</b>				
birth_country_cd	A code indicating the country of birth.	COUNTRY_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, LEGACY_CONSENT, LEGACY_TTH	Optional
birth_country_usd	A code indicating the specific U.S. dependency of birth.	COUNTRY_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, LEGACY_CONSENT, LEGACY_TTH	Optional
birth_sex	The person's biological sex at birth, as noted on the birth certificate.	F - Female M - Male	YES	All	Required



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		U - Unknown			
current_gender	The person's current gender or psychosocial construct that most people use to classify a person as male, female, both, or neither. When eHARS is first installed and configured, the state determines whether or not this field is displayed.	F - Female FM - Transgender-Female to Male U - Unknown M - Male MF - Transgender-Male to Female AD - Additional Gender Identity	YES	All except BC	Required
current_sex	Physiological anatomy and biology that determines if someone is male, female, or intersexed. At installation, the state determines whether or not this field is displayed.	F - Female I - Intersexed M - Male	YES	All except BC	Retired
dob	The first known date of birth.	YYYYMMDD	YES	All	Required
dob_alias	The second known or alias date of birth.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, LEGACY_CONSENT, LEGACY_TTH	Optional
doc_belongs_to	Indicates if the demographics data belong to PERSON, MOTHER, FATHER, or CHILDn.	PERSON, MOTHER, FATHER, CHILDn	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC	System
document_uid	A unique identifier for a document.		YES	All	System
education	The level of education (optional field).	1 - 8th grade or less 2 - Some high school 3 - High school graduate, GED or equivalent 4 - Some college 5 - College degree 6 - Post-graduate work 7 - Some school, level unknown	NO	All except BC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		9 - Unknown			
ethnicity1	Indicates if the person is of Hispanic or Latino origin. A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.	ETHNICITY	YES	All	Required
ethnicity2	Indicates if the person is of Hispanic or Latino origin. A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.	ETHNICITY	YES	All	Optional
gender_id_dt	The date the gender identity of the person was identified.	YYYYMMDD	YES	All except BC	Required
gender_other_specify	User entered gender identity when "other specify" is chosen.		YES	All except BC	Required
hars_race	For legacy HARS data, a read-only field indicating the person's race code entered in HARS previous to v6.0 (prior to implementation of Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity [ <a href="http://www.whitehouse.gov/omb/fedrereg/ombdir15.html">http://www.whitehouse.gov/omb/fedrereg/ombdir15.html</a> ]).	1-White, not Hispanic 2-Black, not Hispanic 3-Hispanic 4-Asian/Pacific Islander 5-American Indian/Alaska Native 9-Unknown	YES	LEGACY_ADULT, LEGACY_PEDIATRIC	Legacy HARS
hars_xrace	HARS expanded race.	HARS_XRACE	YES	LEGACY_ADULT, LEGACY_PEDIATRIC	Legacy HARS
hcw	Is this person a healthcare worker? (optional field)	YES_NO_UNK	YES	ACRF	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
hcw_occup	Occupation, if healthcare worker (optional field).	OCCUPATION	YES	ACRF, LEGACY_CONSENT, LEGACY_TTH	Optional
marital_status	The person's marital status.	A - Married and separated D - Divorced M - Married N - Not otherwise specified O - Other S - Single and never married U - Unknown W - Widowed	NO	All except PCRF	Optional
race1	Indicates the person's race.	RACE	YES	All	Required
race2	Indicates the person's race.	RACE	YES	All	Required
race3	Indicates the person's race.	RACE	YES	All	Required
race4	Indicates the person's race.	RACE	YES	All	Required
race5	Indicates the person's race.	RACE	YES	All	Required
sexual_orientation	The person's sexual orientation	SEXUAL_ORIENTATION	YES	All except BC	Required
sexual_orientation_id_dt	The date the sexual orientation of the person was identified.	YYYYMMDD	YES	All except BC	Required
sexual_orientation_other_spec	Use entered sexual orientation when "other specify" is chosen.		YES	All except BC	Required
vital_status	Indicates vital status at time form was completed—alive, dead, or unknown.	1 - Alive 2 - Dead 9 - Unknown	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC	Required
<b>PERSON_NAME</b>	<b>A table that maintains information on a person's names and Soundex codes.</b>				

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
doc_belongs_to	Indicates if the name belongs to PERSON, MOTHER, or CHILDn.	PERSON, MOTHER, CHILDn	YES	All	System
document_uid	A unique identifier for a document.		YES	All	System
first_name	The person's first name.		NO	All	Optional
first_name_sndx	The person's first name in a Soundex format.		NO	All	System
last_name	The person's last name. For hyphenated or last names containing two words, the standard is as follows: Smith Jones.		NO	All	Required
last_name_sndx	The person's last name in a Soundex format.		YES	All	System
middle_name	The person's middle name.		NO	All	Optional
name_prefix	The person's name prefix.		NO	All	Optional
name_suffix	The person's name suffix.		NO	All	Optional
name_use_cd	A code indicating the type of name being used, such as Maiden or Birth. The default value is Legal.	NAME_USE	YES	All	Optional
person_name_seq	Sequence identifiers for a person's name.	0-999,999,999	YES	All	System
removal_ind	A field used by the application to determine if the name removal utility has been applied to this row.	YES_NO	NO		System
<b>PREGNANCY_OUTCOME</b>	<b>A table to capture final outcome of previous pregnancies of birthing person.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
preg_outcome	Final outcome of pregnancy.	PREGNANCY_OUTCOME	YES	PCRF, LEGACY_PEDIATRIC	Optional
preg_seq	Auto-generated number to allow for multiple events per document.	0-9	YES	PCRF, LEGACY_PEDIATRIC	System
preg_outcome_dt	Year in which pregnancy event occurred.	YYYY.... YYYYMMDD 99999999	YES	PCRF, LEGACY_PEDIATRIC	Optional
<b>PRETEST_QUESTIONNAIRE</b>	<b>A table that maintains information on a person's pretest questionnaire.</b>				
document_uid	A unique identifier for the person's Pretest Questionnaire.		YES	ACRF, LEGACY_TTH	System
qhrtnw	Are you now taking any ARVs?	YES_NO	YES	ACRF, LEGACY_TTH	Optional
Ucts	Main source of testing history information.	UCTS	YES	ACRF, LEGACY_TTH	Required
ufposa	When you first tested positive for HIV, was the HIV test an anonymous test?	YES_NO_REF	YES	ACRF, LEGACY_TTH	Optional
ufposd	Date of first positive HIV test		YES	ACRF, LEGACY_TTH	Required
ufposd_self	First positive test result from self-test performed by patient	YES_NO_UNK	YES	ACRF	Required
ufps_site	Name of facility where first tested positive for HIV	SITE_CD	NO	ACRF, LEGACY_TTH	Optional
ufps_state	State where first tested positive for HIV	STATE_CODES_PR	YES	ACRF, LEGACY_TTH	Optional
ufpstyp	Type of facility where first tested positive for HIV	FACILITY_TYPE	YES	ACRF, LEGACY_TTH	Optional
uftstd	When was the first time you ever got tested for HIV?		YES	ACRF, LEGACY_TTH	Optional
ulstnd	Date of last negative HIV test		YES	ACRF, LEGACY_TTH	Required
ulstnd_sef	Last negative test result from a self-test performed by patient	YES_NO_UNK	YES	ACRF	Required
ulstngs	Type of facility where last tested negative for HIV	FACILITY_TYPE	YES	ACRF, LEGACY_TTH	Optional
ulstngs_site	Name of facility where last tested negative for HIV	SITE_CD	NO	ACRF, LEGACY_TTH	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
ulstngs_state	State where last tested negative for HIV	STATE_CODES_PR	YES	ACRF, LEGACY_TTH	Optional
ungtst	Ever had a negative HIV test?	YES_NO_REF_UNK	YES	ACRF, LEGACY_TTH	Required
unumtsts	Number of negative HIV tests within 24 months before first positive test	0-99	YES	ACRF, LEGACY_TTH	Required
unumtsts_self	Number of negative test results were self-tests performed by patient	0-99	YES	ACRF	Required
upastp	Ever had a positive HIV test result?	YES_NO_REF	YES	ACRF, LEGACY_TTH	Required
upnumtsts	For persons who had a previous positive test (Legacy Pre-test form only): In the two years before your first positive test, how many times did you get tested for HIV?	0-99	YES	ACRF, LEGACY_TTH	Legacy Incidence
uptests	Have you been tested for HIV before today?	YES_NO_REF	YES	ACRF, LEGACY_TTH	Optional
uqintd	Date patient reported information		YES	ACRF, LEGACY_TTH	Required
ur3_5sp	Reason for getting today's HIV test: If other reason, describe		YES	ACRF, LEGACY_TTH	Optional
ur4e_5sp	Reason for getting the first positive HIV test: If other reason, describe		YES	ACRF, LEGACY_TTH	Optional
ureas3_1	Reason for getting today's HIV test: Think you might have been exposed to HIV in the 6 months before the test	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_2	Reason for getting today's HIV test: Get tested on a regular basis and it is time to get tested again	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_3	Reason for getting today's HIV test: Just checking to make sure you are HIV negative	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_4	Reason for getting today's HIV test: Required by insurance, military, court, or other agency	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_5	Reason for getting today's HIV test: Other reason you want to get tested	YES_NO	YES	ACRF, LEGACY_TTH	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
urs4e_1	Reason for getting the first positive HIV test: Thought you might have been exposed to HIV in the past 6 months before the test	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_2	Reason for getting the first positive HIV test: Got tested on a regular basis and it was time to get tested again	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_3	Reason for getting the first positive HIV test: Just checking to make sure you were HIV negative	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_4	HIV test required	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_5	Reason for getting the first positive HIV test: Other reason you wanted to get tested	YES_NO	YES	ACRF, LEGACY_TTH	Optional
<b>PROVIDER_CODE</b>	<b>A table that maintains information on healthcare providers.</b>				
first_name	The first name of the healthcare provider.		NO	N/A	Optional
last_name	The last name of the healthcare provider.		NO	N/A	Optional
middle_name	The middle name of the healthcare provider.		NO	N/A	Optional
name_prefix	The name prefix of the healthcare provider.		NO	N/A	Optional
name_suffix	The name suffix of the healthcare provider.		NO	N/A	Optional
phone	The phone number of the healthcare provider.	7 or 10 digits	NO	N/A	Optional
provider_uid	A unique identifier for a healthcare provider.		NO	N/A	System
ship_flag	A field used by the application to determine if the information needs to be transferred to CDC		NO	N/A	System
specialty_cd	A code indicating the type of specialty for this health care provider.	SPECIALTY_CD	YES	N/A	Optional
<b>RIDR</b>	<b>A table that maintains information pertaining to a case's duplicate status review.</b>				

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
comments	Notes or comments pertaining to the duplicate status information entered for this person.		NO	ACRF, PCRF	Optional
document_uid	A unique identifier of the current document.		YES	ACRF, PCRF	System
duplicate_status	The status of the duplicate review, such as Pending or Same As.	1 - Same as 2 - Different than 3 - Pending	YES	ACRF, PCRF	Required if case identified as potential duplicate
ehars_uid	A unique identifier for the existing case.		YES	ACRF, PCRF	System
last_verify_dt	The date when the status of the duplicate review was last verified.	YYYYMMDD	YES	ACRF, PCRF	Optional
state_cd	The two character postal code of the state of the possible duplicate case.	STATE_CODES_PR	YES	ACRF, PCRF	Required if case identified as potential duplicate
stateno	The stateno identifier of the possible duplicate case.		YES	ACRF, PCRF	Required if case identified as potential duplicate
verify_by	The person who reviewed the duplicate status entry.		YES	ACRF, PCRF	Optional
<b>RISK</b>	<b>A table that maintains information on a person's risk factors.</b>				
cophi_status	Code that indicates the COPHI investigation status, if applicable.	1 - Open, under investigation 2 - Closed, confirmed COPHI 3 - Closed, investigated, not confirmed 4 - Closed, not a COPHI 5 - Will not be investigated, not confirmed 9 - Unknown	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
detail	This field captures detailed information about risk factor—the type of clotting factor the person had or the occupation, if occupational exposure. <b>Note:</b> RISK.detail also stores NIR type information (1 = user entered [if date investigation was completed is entered], 2 = system assigned)	For R04, R30, R33, R32 => CLOTTING_FACTOR For R13 => OCCUPATION For R80, R81 => 1 = user entered [if date investigation was completed is entered], 2 = system assigned	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Optional
display	A field used by the application for display purposes.	A(adult), P(pediatric), H(hemophilia)	NO	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	System
document_uid	A unique identifier for a document.		YES	All	System
resolution_dt	The date the COPHI investigation was resolved.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Optional
risk_cd	Code indicating a risk factor (such as R03 indicating IDU).	RISK_CD (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Refer to RISK_CD table for requirements for each variable
risk_seq	Sequence identifier for a person's modes of exposure.	0-99,999,999	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	System
risk_value	Code indicating the risk factor value (Y-Yes, N-No, U-Unknown, or 2-CDC confirmed) or the mother's infection status (1–9).	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Refer to RISK_CD table for valid data element values for each variable

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
trans_first_dt	If patient received transfusion of blood/blood components, the first date the patient received transfusion. <b>Note:</b> For user entered NIR (No Identified Risk), the date entered is stored in this field.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
trans_last_dt	If patient received transfusion of blood/blood components, the last date the patient received transfusion. <b>Note:</b> When the system identifies NIR, the system date is stored in this field.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
<b>RISK_CD</b>	<b>A table that contains all distinct RISK.risk_cd values and associated descriptions.</b>				
R01	Sex with male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R02	Sex with female	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R03	Injected non-prescription drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R04	Received clotting factor for hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R05	Heterosexual contact with person who injected drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC,	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
				LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	
R06	Heterosexual contact with bisexual male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R07	Heterosexual contact with person with hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R08	Heterosexual contact with transfusion recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R09	Heterosexual contact with transplant recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R10	Heterosexual contact with person with AIDS or documented HIV infection, risk not specified	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R11	Received transfusion of blood/blood components (other than clotting factor)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R12	Received transplant of tissue/organs or artificial insemination	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
R13	Worked in a health care or clinical laboratory setting	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R14	Sexual contact with male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R15	Sexual contact with female	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R16	Child's biological mother's infection status	For R16 only => M_INFECTION_STATUS	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R17	Perinatally acquired HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R18	Injected non-prescription drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R19	Heterosexual contact with person who injected drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
R20	Heterosexual contact with bisexual male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R21	Heterosexual contact with male with hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R22	Heterosexual contact with transfusion recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R23	Heterosexual contact with transplant recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R24	Heterosexual contact with male with AIDS or documented HIV infection, risk not specified	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R25	Received transfusion of blood/blood components (other than clotting factor)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R26	Received transplant or tissue/organs or artificial insemination	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R27	Injected non-prescription drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT,	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
				LEGACY_PEDIATRIC, BC, DEATH_DOC	
R30	Received clotting factor for hemophilia/coagulation disorder (LEGACY)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R32	Received clotting factor for hemophilia/coagulation disorder (LEGACY)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R33	Received clotting factor for hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R34	Received transfusion of blood/blood components (other than clotting factor)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R35	Received transplant of tissue/organs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R36	Child breastfed/chestfed by birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R37	Child received premasticated/pre- chewed food from birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT,	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
				LEGACY_PEDIATRIC, BC, DEATH_DOC	
R38	Child breastfed/chestfed by non- birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R39	Child received premasticated/pre- chewed food from non-birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R40	Adult other documented risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R41	Child other documented risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R80	Adult no identified risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R81	Child no identified risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
<b>SUBSTANCE_HISTORY</b>	<b>A table that maintains the toxicology data of birthing person and infant during pregnancy, labor and delivery. This information is collected in the Birth History and Birthing Person History sections of Pediatric Case Report Forms (PCRF) documents.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
substance_seq	Sequence number.		YES	PCRF, LEGACY_PEDIATRIC	System
doc_belongs_to	Indicates who the substance data belongs to: PERSON or MOTHER.	MOTHER, PERSON	YES	PCRF, LEGACY_PEDIATRIC	System
substance_event_cd	Code to determine if and when substance was tested for use or injection by mother or person.	SUBSTANCE_EVENT_C D	YES	PCRF, LEGACY_PEDIATRIC	System
substance_cd	Substance code used or injected by person.	SUBSTANCE_CD	YES	PCRF, LEGACY_PEDIATRIC	Optional
substance_value	Result value selected.	SUBSTANCE_USE_RESULT SUBSTANCE_SCREEN_RESU LT	YES	PCRF, LEGACY_PEDIATRIC	Optional
substance_detail	User entered substance name when Other (specify) code is chosen.	alphanumeric, NULL, blank	YES	PCRF, LEGACY_PEDIATRIC	Optional
substance_dt	Date of substance screening or use.	YYYYMMDD	YES	PCRF, LEGACY_PEDIATRIC	Optional



**National HIV Surveillance System (NHSS)**

Attachment 3(a)

Adult HIV Confidential Case Report Form

**I. Patient Identification (record all dates as mm/dd/yyyy)**

*First Name	*Middle Name	*Last Name	Last Name Soundex
Alternate Name Type (ex: Alias, Married)	*First Name	*Middle Name	*Last Name
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary	*Current Address, Street		Address Date ____/____/____
*Phone (____)	City	County	State/Country
*Medical Record Number		*Other ID Type	*Number

U.S. Department of Health  
and Human Services**Adult HIV Confidential Case Report Form**  
(Patients ≥13 years of age at time of diagnosis) \*Information NOT transmitted to CDCCenters for Disease Control  
and Prevention (CDC)**II. Health Department Use Only (record all dates as mm/dd/yyyy)**

Form approved OMB no. NNNN-NNNN Exp. MM/DD/YYYY

Date Received at Health Department ____/____/____	eHARS Document UID	State Number
Reporting Health Dept—City/County		City/County Number
Document Source	Surveillance Method <input type="checkbox"/> Active <input type="checkbox"/> Passive <input type="checkbox"/> Follow up <input type="checkbox"/> Reabstraction <input type="checkbox"/> Unknown	
Did this report initiate a new case investigation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Report Medium <input type="checkbox"/> 1-Field visit <input type="checkbox"/> 2-Mailed <input type="checkbox"/> 3-Faxed <input type="checkbox"/> 4-Phone <input type="checkbox"/> 5-Electronic transfer <input type="checkbox"/> 6-CD/disk	

**III. Facility Providing Information (record all dates as mm/dd/yyyy)**

Facility Name		*Phone (____)
*Street Address		
City	County	State/Country
		*ZIP Code
Facility Type <u>Inpatient:</u> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____	<u>Outpatient:</u> <input type="checkbox"/> Private physician's office <input type="checkbox"/> Adult HIV clinic <input type="checkbox"/> Other, specify _____	<u>Screening, Diagnostic, Referral Agency:</u> <input type="checkbox"/> CTS <input type="checkbox"/> STD clinic <input type="checkbox"/> Other, specify _____
<u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____		
Date Form Completed ____/____/____	*Person Completing Form	*Phone (____)

**IV. Patient Demographics (record all dates as mm/dd/yyyy)**

Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	Country of Birth <input type="checkbox"/> US <input type="checkbox"/> Other/US dependency (specify) _____	
Date of Birth ____/____/____	Alias Date of Birth ____/____/____	
Vital Status <input type="checkbox"/> 1-Alive <input type="checkbox"/> 2-Dead	Date of Death ____/____/____	State of Death
Gender Identity <input type="checkbox"/> Man <input type="checkbox"/> Woman <input type="checkbox"/> Transgender man <input type="checkbox"/> Transgender woman <input type="checkbox"/> Additional gender identity (specify) _____ <input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown		
Date Identified ____/____/____		
Sexual Orientation <input type="checkbox"/> Straight or heterosexual <input type="checkbox"/> Lesbian or gay <input type="checkbox"/> Bisexual <input type="checkbox"/> Additional sexual orientation (specify) _____ <input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown		
Date Identified ____/____/____		
Ethnicity <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino <input type="checkbox"/> Unknown	Expanded Ethnicity	
Race (check all that apply) <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown	Expanded Race	

**V. Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)**

Address Event Type (check all that apply to address below) <input type="checkbox"/> Residence at HIV diagnosis <input type="checkbox"/> Residence at stage 3 (AIDS) diagnosis <input type="checkbox"/> Check if <u>SAME</u> as current address			
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary			
*Street Address			
City	County	State/Country	*ZIP Code

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0573). **Do not send the completed form to this address.**

<b>Diagnosis Type</b> (check all that apply to facility below) <input type="checkbox"/> HIV <input type="checkbox"/> Stage 3 (AIDS) <input type="checkbox"/> Check if <u>SAME</u> as facility providing information			
<b>Facility Name</b>		<b>*Phone (      )</b>	
<b>*Street Address</b>			
<b>City</b>	<b>County</b>	<b>State/Country</b>	<b>*ZIP Code</b>
<b>Facility Type</b> <u>Inpatient:</u> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____	<u>Outpatient:</u> <input type="checkbox"/> Private physician's office <input type="checkbox"/> Adult HIV clinic <input type="checkbox"/> Other, specify _____	<u>Screening, Diagnostic, Referral Agency:</u> <input type="checkbox"/> CTS <input type="checkbox"/> STD clinic <input type="checkbox"/> Other, specify _____	<u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____
<b>*Provider Name</b>		<b>*Provider Phone (      )</b>	<b>Specialty</b>

After 1977 and before the earliest known diagnosis of HIV infection, this patient had:			
Sex with male	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Sex with female	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Injected nonprescription drugs	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Received clotting factor for hemophilia/coagulation disorder	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Specify clotting factor: _____	Date received ____ / ____ / _____		
<b>HETEROSEXUAL relations with any of the following:</b>			
HETEROSEXUAL contact with person who injected drugs	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
HETEROSEXUAL contact with bisexual male	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
First date received ____ / ____ / _____ Last date received ____ / ____ / _____			
Received transplant of tissue/organs or artificial insemination	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Worked in a healthcare or clinical laboratory setting	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
If occupational exposure is being investigated or considered as primary mode of exposure, specify occupation and setting: _____			
Other documented risk (include detail in Comments) _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

<b>Suspect acute HIV infection?</b> <i>If YES, complete the two items below; enter documented negative HIV test result data in Laboratory Data section, and enter patient or provider report of previous negative HIV test result in HIV Testing History section</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)?   Date of sign/symptom onset ____/____/____		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Other evidence suggestive of acute HIV infection? <i>If YES, describe:</i> _____ Date of evidence ____/____/____		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

Diagnosis	Dx Date	Diagnosis	Dx Date	Diagnosis	Dx Date
Candidiasis, bronchi, trachea, or lungs		Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, <u>pneumonitis</u> , or esophagitis		M. tuberculosis, pulmonary <sup>1</sup>	
Candidiasis, esophageal		Histoplasmosis, disseminated or extrapulmonary		M. tuberculosis, disseminated or extrapulmonary <sup>1</sup>	
Carcinoma, invasive cervical		Isosporiasis, chronic intestinal (>1 mo. duration)		Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Coccidioidomycosis, disseminated or extrapulmonary		Kaposi's sarcoma		Pneumocystis pneumonia	
Cryptococcosis, extrapulmonary		Lymphoma, Burkitt's (or equivalent)		Pneumonia, recurrent, in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, immunoblastic (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, primary in brain		Salmonella septicemia, recurrent	
Cytomegalovirus retinitis (with loss of vision)		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary		Toxoplasmosis of brain, onset at >1 mo. of age	
HIV encephalopathy				Wasting syndrome due to HIV	

<b>HIV Immunoassays</b>	
<b>TEST</b> <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-2 IA	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	<b>Collection Date</b> ____/____/____
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	

**IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy) (cont)**

<b>TEST</b> <input type="checkbox"/> HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab)	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <b>Overall:</b> <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	<b>Collection Date</b> ____/____/____
<b>Analyte results:</b> HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive HIV-1/2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <sup>3</sup> <b>Overall interpretation:</b> <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Index Value _____	<b>Collection Date</b> ____/____/____
<b>Analyte results:</b> HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Not reportable due to high Ab level <b>Index Value</b> _____	
HIV-1 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated <b>Index Value</b> _____	
HIV-2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated <b>Index Value</b> _____	
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1/2 type-differentiating immunoassay (supplemental) (differentiates between HIV-1 Ab and HIV-2 Ab)	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <sup>4</sup> <b>Overall interpretation:</b> <input type="checkbox"/> HIV positive, untypable <input type="checkbox"/> HIV-1 positive with HIV-2 cross-reactivity <input type="checkbox"/> HIV-2 positive with HIV-1 cross-reactivity	
<input type="checkbox"/> HIV negative <input type="checkbox"/> HIV indeterminate <input type="checkbox"/> HIV-1 indeterminate <input type="checkbox"/> HIV-2 indeterminate <input type="checkbox"/> HIV-1 positive <input type="checkbox"/> HIV-2 positive	
<b>Analyte results:</b> HIV-1 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate <b>Collection Date</b> ____/____/____	
HIV-2 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 WB	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	<b>Collection Date</b> ____/____/____
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>HIV Detection Tests</b>	
<b>TEST</b> <input type="checkbox"/> HIV-1/2 RNA NAAT (Qualitative)	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> Both (HIV-1 and HIV-2) <input type="checkbox"/> HIV, not differentiated (HIV-1 or HIV-2) <input type="checkbox"/> Neither (negative)	<b>Collection Date</b> ____/____/____
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 RNA NAAT (Qualitative and Quantitative)	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <b>Qualitative:</b> <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	<b>Collection Date</b> ____/____/____
<b>Analyte results:</b> HIV-1 Quantitative: <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit	
<b>Copies/mL</b> _____ <b>Log</b> _____	
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-1 culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-2 culture	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	<b>Collection Date</b> ____/____/____
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative) <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Quantitative)	
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Result</b> <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit <input type="checkbox"/> Not detected	<b>Copies/mL</b> _____ <b>Log</b> _____
<b>Collection Date</b> ____/____/____	
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>Drug Resistance Tests (Genotypic)</b>	
<b>TEST</b> <input type="checkbox"/> HIV-1 Genotype (Unspecified)	<b>Test Brand Name/Manufacturer</b> _____
<b>Lab Name</b> _____	<b>Facility Name</b> _____
<b>Provider Name</b> _____	<b>Collection Date</b> ____/____/____
<b>Immunologic Tests (CD4 count and percentage)</b>	
<b>CD4 count</b> _____ cells/μL <b>CD4 percentage</b> _____ %	<b>Collection Date</b> ____/____/____
<b>Test Brand Name/Manufacturer</b> _____	<b>Lab Name</b> _____
<b>Facility Name</b> _____	<b>Provider Name</b> _____
<b>Documentation of Tests</b>	
<b>Did documented laboratory test results meet approved HIV diagnostic algorithm criteria?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
<b>If YES, provide specimen collection date of earliest positive test result for this algorithm</b> ____/____/____	
<i>Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.</i>	
<b>Is earliest evidence of HIV infection diagnosis documented by a physician rather than by laboratory test results?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
<b>If YES, provide date of diagnosis by physician</b> ____/____/____	
<b>Date of last documented negative HIV test result</b> (before HIV diagnosis date) ____/____/____	
<b>Specify type of test:</b> _____	
<b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	

<sup>2</sup>Results not directly observed by a provider should be recorded in HIV Testing History.<sup>3</sup>Complete the overall interpretation and the analyte results.<sup>4</sup>Always complete the overall interpretation. Complete the analyte results when available.

X. Treatment/Services Referrals (record all dates as mm/dd/yyyy)

Has this patient been informed of his/her HIV infection? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		This patient's partners will be notified about their HIV exposure and counseled by <input type="checkbox"/> 1-Health dept <input type="checkbox"/> 2-Physician/Provider <input type="checkbox"/> 3-Patient <input type="checkbox"/> 9-Unknown	
Evidence of receipt of HIV medical care other than laboratory test result (select one; record additional evidence in Comments) <input type="checkbox"/> 1-Yes, documented <input type="checkbox"/> 2-Yes, client self-report, only   Date of medical visit or prescription   __/__/____			
For Female Patient			
This patient is receiving or has been referred for gynecological or obstetrical services <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Is this patient currently pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Has this patient delivered live-born infants? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
For Children of Patient (record most recent birth in these boxes; record additional or multiple births in Comments)			
*Child's Name		Child's Date of Birth   __/__/____	
Child's Last Name Soundex		Child's State Number	
Facility Name of Birth (if child was born at home, enter "home birth")		*Phone (   )	
Facility Type <u>Inpatient:</u> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____		<u>Outpatient:</u> <input type="checkbox"/> Other, specify _____	
		<u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____	
*Street Address		*ZIP Code	
City		State/Country	

XI. Antiretroviral Use History (record all dates as mm/dd/yyyy)

Main source of antiretroviral (ARV) use information (select one) <input type="checkbox"/> Patient interview <input type="checkbox"/> Medical record review <input type="checkbox"/> Provider report <input type="checkbox"/> NHM&E <input type="checkbox"/> Other		Date patient reported information ____/____/____	
Ever taken any ARVs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
If yes, reason for ARV use (select all that apply)			
<input type="checkbox"/> HIV Tx	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____
<input type="checkbox"/> PrEP	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____
<input type="checkbox"/> PEP	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____
<input type="checkbox"/> PMTCT	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____
<input type="checkbox"/> HBV Tx	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____
<input type="checkbox"/> Other (specify reason) _____			
	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____

XII. HIV Testing History (record all dates as mm/dd/yyyy)

Main source of testing history information (select one) <input type="checkbox"/> Patient interview <input type="checkbox"/> Medical record review <input type="checkbox"/> Provider report <input type="checkbox"/> NHM&E <input type="checkbox"/> Other		Date patient reported information ____/____/____	
Ever had previous positive HIV test result? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Date of first positive HIV test result   ____/____/____	
Was the first positive test result from a self-test performed by the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
Ever had a negative HIV test result? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Date of last negative HIV test result (if date is from a lab test with test type, enter in Lab Data section)   ____/____/____	
Was the last negative test result from a self-test performed by the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
Number of negative HIV test results within the 24 months before the first positive test result   __ <input type="checkbox"/> Unknown			
How many of these negative test results were from self-tests performed by the patient?   __ <input type="checkbox"/> Unknown			

XIII. Comments


XIV. \*Local/Optional Fields


This report to CDC is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV. Information in CDC's National HIV Surveillance System that would permit identification of any individual on whom a record is maintained is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).

**National HIV Surveillance System (NHSS)**

Attachment 3(b)

Pediatric HIV Confidential Case Report Form

**I. Patient Identification (record all dates as mm/dd/yyyy)**

*First Name	*Middle Name	*Last Name	Last Name Soundex
Alternate Name Type (example: Birth, Call Me)	*First Name	*Middle Name	*Last Name
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary	*Current Address, Street		Address Date ____/____/____
*Phone (____)	City	County	State/Country
*Medical Record Number		*Other ID Type	*Number

U.S. Department of Health  
and Human Services**Pediatric HIV Confidential Case Report Form**  
(Patients aged <13 years at time of perinatal exposure or patients aged <13 years at time of  
diagnosis) \*Information NOT transmitted to CDCCenters for Disease Control  
and Prevention (CDC)**II. Health Department Use Only (record all dates as mm/dd/yyyy)**

Form approved OMB no. NNNN-NNNN Exp. MM/DD/YYYY

Date Received at Health Department ____/____/____	eHARS Document UID	State Number
Reporting Health Dept—City/County	City/County Number	
Document Source	Surveillance Method <input type="checkbox"/> Active <input type="checkbox"/> Passive <input type="checkbox"/> Follow up <input type="checkbox"/> Reabstraction <input type="checkbox"/> Unknown	
Did this report initiate a new case investigation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Report Medium <input type="checkbox"/> 1-Field visit <input type="checkbox"/> 2-Mailed <input type="checkbox"/> 3-Faxed <input type="checkbox"/> 4-Phone <input type="checkbox"/> 5-Electronic transfer <input type="checkbox"/> 6-CD/disk	

**III. Facility Providing Information (record all dates as mm/dd/yyyy)**

Facility Name		*Phone (____)
*Street Address		
City	County	State/Country
Facility Type <i>Inpatient:</i> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____	<i>Outpatient:</i> <input type="checkbox"/> Private physician's office <input type="checkbox"/> Pediatric clinic <input type="checkbox"/> Pediatric HIV clinic <input type="checkbox"/> Other, specify _____	<i>Other Facility:</i> <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____
Date Form Completed ____/____/____	*Person Completing Form	*Phone (____)

**IV. Patient Demographics (record all dates as mm/dd/yyyy)**

Diagnostic Status at Report <input type="checkbox"/> 3-Perinatal HIV exposure <input type="checkbox"/> 4-Pediatric HIV <input type="checkbox"/> 5-Pediatric AIDS <input type="checkbox"/> 6-Pediatric seroreverter	Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	Country of Birth <input type="checkbox"/> US <input type="checkbox"/> Other/US dependency (specify) _____
Date of Birth ____/____/____	Alias Date of Birth ____/____/____	
Vital Status <input type="checkbox"/> 1-Alive <input type="checkbox"/> 2-Dead	Date of Death ____/____/____	State of Death
Date of Last Medical Evaluation ____/____/____	Date of Initial Evaluation for HIV ____/____/____	
Gender Identity <input type="checkbox"/> Boy <input type="checkbox"/> Girl <input type="checkbox"/> Transgender boy <input type="checkbox"/> Transgender girl <input type="checkbox"/> Additional gender identity (specify) _____ <input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown		
Date Identified ____/____/____		
Sexual Orientation <input type="checkbox"/> Straight or heterosexual <input type="checkbox"/> Lesbian or gay <input type="checkbox"/> Bisexual <input type="checkbox"/> Additional sexual orientation (specify) _____ <input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown		
Date Identified ____/____/____		
Ethnicity <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino <input type="checkbox"/> Unknown	Expanded Ethnicity	
Race <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American (check all that apply) <input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown	Expanded Race	

**V. Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)**

Address Event Type (check all that apply to address below)	<input type="checkbox"/> Residence at HIV diagnosis	<input type="checkbox"/> Residence at stage 3 (AIDS) diagnosis	<input type="checkbox"/> Residence at perinatal exposure	<input type="checkbox"/> Residence at pediatric seroreverter	<input type="checkbox"/> Check if <u>SAME</u> as current address
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary					
*Street Address					
City	County	State/Country	*ZIP Code		

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0573). **Do not send the completed form to this address.**

This report to CDC is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV. Information in CDC's National HIV Surveillance System that would permit identification of any individual on whom a record is maintained is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).



**VI. Facility of Diagnosis (add additional facilities in Comments)**

<b>Diagnosis Type</b> (check all that apply to facility below) <input type="checkbox"/> HIV <input type="checkbox"/> Stage 3 (AIDS) <input type="checkbox"/> Perinatal exposure <input type="checkbox"/> Check if <u>SAME</u> as facility providing information			
<b>Facility Name</b>			<b>*Phone</b> (   )
<b>*Street Address</b>			
<b>City</b>	<b>County</b>	<b>State/Country</b>	<b>*ZIP Code</b>
<b>Facility Type</b> <u>Inpatient</u> : <input type="checkbox"/> Hospital <u>Outpatient</u> : <input type="checkbox"/> Private physician's office <input type="checkbox"/> Pediatric clinic <u>Other Facility</u> : <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Pediatric HIV clinic <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____			
<b>*Provider Name</b>		<b>*Provider Phone</b> (   )	<b>Specialty</b>

**VII. Patient History (respond to all questions) (record all dates as mm/dd/yyyy)**

<b>Birth person's HIV infection status</b> (select one): <input type="checkbox"/> Refused HIV testing <input type="checkbox"/> Known to be uninfected after this child's birth <input type="checkbox"/> Known HIV+ before pregnancy <input type="checkbox"/> Known HIV+ during pregnancy <input type="checkbox"/> Known HIV+ sometime before birth <input type="checkbox"/> Known HIV+ at delivery <input type="checkbox"/> Known HIV+ after child's birth <input type="checkbox"/> HIV+, time of diagnosis unknown <input type="checkbox"/> HIV status unknown	
<b>Date of birthing person's first positive test result to confirm infection</b> ____/____/____	<b>Child breastfed/chestfed by birthing person</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <b>Child received premasticated/pre-chewed food from birthing person</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>After 1977 and before the earliest known diagnosis of HIV infection, the birthing person had:</b>	
Perinatally acquired HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Injected nonprescription drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>Birthing person had HETEROSEXUAL relations with any of the following:</b>	
HETEROSEXUAL contact with person who injected drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with bisexual male	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>Birthing person had:</b>	
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) First date received ____/____/____   Last date received ____/____/____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received transplant of tissue/organs or artificial insemination	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>Before the diagnosis of HIV infection, this child had:</b>	
Injected nonprescription drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received clotting factor for hemophilia/coagulation disorder Specify clotting factor: _____   Date received ____/____/____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) First date received ____/____/____   Last date received ____/____/____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received transplant of tissue/organs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Sexual contact with male	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Sexual contact with female	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Been breastfed/chestfed by non-birthing person	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received premasticated/pre-chewed food from non-birthing person	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Other documented risk (include detail in Comments)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

**VIII. Clinical: Opportunistic Illnesses (record all dates as mm/dd/yyyy)**

Diagnosis	Dx Date	Diagnosis	Dx Date	Diagnosis	Dx Date
Bacterial infection, multiple or recurrent (including Salmonella septicemia)		HIV encephalopathy		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary	
Candidiasis, bronchi, trachea, or lungs		Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis		M. tuberculosis, pulmonary <sup>1</sup>	
Candidiasis, esophageal		Histoplasmosis, disseminated or extrapulmonary		M. tuberculosis, disseminated or extrapulmonary <sup>1</sup>	
Carcinoma, invasive cervical		Isosporiasis, chronic intestinal (>1 mo. duration)		Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Coccidioidomycosis, disseminated or extrapulmonary		Kaposi's sarcoma		Pneumocystis pneumonia	
Cryptococcosis, extrapulmonary		Lymphoid interstitial pneumonia and/or pulmonary lymphoid		Pneumonia, recurrent in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, Burkitt's (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, immunoblastic (or equivalent)		Toxoplasmosis of brain, onset at >1 mo. of age	
Cytomegalovirus retinitis (with loss of vision)		Lymphoma, primary in brain		Wasting syndrome due to HIV	

<sup>1</sup>If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:



**IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)**

<b>HIV Immunoassays</b>			
TEST <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-2 IA			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate		Collection Date ____/____/____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab)			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result Overall: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive		Collection Date ____/____/____	
Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive HIV-1/2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive			
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result <sup>3</sup> Overall interpretation: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Index Value _____		Collection Date ____/____/____	
Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Not reportable due to high Ab level Index Value _____			
HIV-1 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated Index Value _____			
HIV-2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated Index Value _____			
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1/2 type-differentiating immunoassay (supplemental) (differentiates between HIV-1 Ab and HIV-2 Ab)			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result <sup>4</sup> Overall interpretation: <input type="checkbox"/> HIV positive, untypable <input type="checkbox"/> HIV-1 positive with HIV-2 cross-reactivity <input type="checkbox"/> HIV-2 positive with HIV-1 cross-reactivity			
<input type="checkbox"/> HIV negative <input type="checkbox"/> HIV indeterminate <input type="checkbox"/> HIV-1 indeterminate <input type="checkbox"/> HIV-2 indeterminate <input type="checkbox"/> HIV-1 positive <input type="checkbox"/> HIV-2 positive			
Analyte results: HIV-1 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate Collection Date ____/____/____			
HIV-2 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate			
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 WB			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate		Collection Date ____/____/____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
<b>HIV Detection Tests</b>			
TEST <input type="checkbox"/> HIV-1/2 RNA NAAT (Qualitative)		Lab Name _____	
Test Brand Name/Manufacturer _____		Provider Name _____	
Facility Name _____		Collection Date ____/____/____	
Result <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> Both (HIV-1 and HIV-2) <input type="checkbox"/> HIV, not differentiated (HIV-1 or HIV-2) <input type="checkbox"/> Neither (negative)			
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1 RNA NAAT (Qualitative and Quantitative)			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result Qualitative: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive		Collection Date ____/____/____	
Analyte results: HIV-1 Quantitative: <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit			
Copies/mL _____ Log _____			
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-1 culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-2 culture			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate		Collection Date ____/____/____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
TEST <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative) <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Quantitative)			
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	
Result <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit <input type="checkbox"/> Not detected		Copies/mL _____ Log _____	
Collection Date ____/____/____			
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample			
<b>Drug Resistance Tests (Genotypic)</b>			
TEST <input type="checkbox"/> HIV-1 Genotype (Unspecified)		Test Brand Name/Manufacturer _____	
Lab Name _____		Facility Name _____	
Provider Name _____		Collection Date ____/____/____	
<b>Immunologic Tests (CD4 count and percentage)</b>			
CD4 count _____ cells/ $\mu$ L		CD4 percentage _____ %	
Collection Date ____/____/____		Collection Date ____/____/____	
Test Brand Name/Manufacturer _____		Lab Name _____	
Facility Name _____		Provider Name _____	

**IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy) (cont)**

<b>Documentation of Tests</b>	
Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
If YES, provide specimen collection date of earliest positive test result for this algorithm ____/____/____ <i>Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.</i>	
Is earliest evidence of diagnosis documented by a physician rather than by laboratory test results?	HIV-infected <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Not HIV-infected <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Date of diagnosis by physician	____/____/____
Date of diagnosis by physician	____/____/____

<sup>2</sup>Results not directly observed by a provider should be recorded in HIV Testing History.<sup>3</sup>Complete the overall interpretation and the analyte results.<sup>4</sup>Always complete the overall interpretation. Complete the analyte results when available.**X. Birth History (for patients exposed perinatally with or without consequent infection)**

Birth history available? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown					
Residence at Birth <input type="checkbox"/> Check if SAME as current address					
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary					
*Street Address	City				
County	State/Country				
*ZIP Code					
Facility of Birth <input type="checkbox"/> Check if SAME as facility providing information					
Facility Name of Birth (if child was born at home, enter "home birth")					
*Phone ( )					
Facility Type	Inpatient: <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____				
Outpatient: <input type="checkbox"/> Other, specify _____	Other Facility: <input type="checkbox"/> Emergency room <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____				
*Street Address	City				
County	State/Country				
*ZIP Code					
Birth History	Birth Weight ____lbs ____oz ____grams				
Type	<input type="checkbox"/> 1-Single <input type="checkbox"/> 2-Twin <input type="checkbox"/> 3-More than two <input type="checkbox"/> 9-Unknown				
Delivery <input type="checkbox"/> Vaginal <input type="checkbox"/> Cesarean <input type="checkbox"/> Unknown					
If Cesarean delivery, mark all the following indications that apply.					
<input type="checkbox"/> HIV indication (high viral load)	<input type="checkbox"/> Previous Cesarean (repeat)				
<input type="checkbox"/> Prolonged labor or failure to progress	<input type="checkbox"/> Birthing person's or physician's preference				
<input type="checkbox"/> Placenta abruptia or p. previa	<input type="checkbox"/> Malpresentation (breech, transverse)				
<input type="checkbox"/> Not specified	<input type="checkbox"/> Fetal distress				
<input type="checkbox"/> Other (e.g., herpes, disproportion) (Specify) _____					
Birth Information	Date				
Rupture of membranes	____/____/____				
Delivery	____/____/____				
Time (use military time: noon = 12:00; midnight = 00:00)					
Congenital Disorders <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If YES, specify types					
Neonatal Status <input type="checkbox"/> 1-Full-term <input type="checkbox"/> 2-Premature <input type="checkbox"/> 9-Unknown					
Neonatal Gestational Age in Weeks ____ (99 = Unknown, 00 = None)					
Was a toxicology screen done on the infant after birth? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If screening for the same substance was done on more than one occasion, record additional dates and results in Comments)	Result				
	Not screened	Date of screen	Positive	Negative	Unknown
	Alcohol	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Amphetamines	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Barbiturates	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Benzodiazepines	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Cocaine	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Crack cocaine	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Fentanyl	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Hallucinogens	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Heroin	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	K2	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Marijuana (cannabis, THC, cannabinoids)	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Methadone	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Methamphetamines	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Nicotine (any tobacco)	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	Opiates	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
	PCP	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify) _____	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	
Specific drug(s) not documented	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	

**XI. Birthing Person History (for patients exposed perinatally with or without consequent infection)**

Birthing Person Date of Birth ____ / ____ / ____		Birthing Person Last Name Soundex	
Birthing Person Country of Birth		Birthing Person State ID Number	
Birthing Person City/County ID Number		*Other Birthing Person ID (specify type of ID and ID number)	
Prenatal Care—Month of Pregnancy Prenatal Care Began (99 = Unknown, 00 = None)		Prenatal Care—Total Number of Prenatal Care Visits (99 = Unknown, 00 = None)	
<b>Has the birthing person ever been pregnant before this pregnancy? Include previous pregnancies that ended in a live birth, miscarriage, stillbirth, or induced abortion.</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
<b>If YES, specify how many previous pregnancies</b>			
		<b>Pregnancy outcome (select one)</b>	
		Miscarriage or Stillbirth	
		Induced abortion	
		Year outcome occurred (9999 = Unknown)	
i.		<input type="checkbox"/>	
ii.		<input type="checkbox"/>	
iii.		<input type="checkbox"/>	
iv.		<input type="checkbox"/>	
v.		<input type="checkbox"/>	
(Record additional pregnancy outcomes in Comments)			
<b>Was a test result (with a specimen collection date within the 6 weeks on or before delivery) documented in the birthing person's labor/delivery record</b>			
CD4 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Quantitative NAAT (RNA or DNA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
<b>Did birthing person receive any antiretrovirals (ARVs) prior to this pregnancy?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown			
Date began ____ / ____ / ____ Date of last use ____ / ____ / ____			
<b>If YES, specify all ARVs</b>			
<b>Did birthing person receive any ARVs during this pregnancy?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown			
Date began ____ / ____ / ____ Date of last use ____ / ____ / ____			
<b>If YES, specify all ARVs</b>			
<b>If NO, select reason</b> <input type="checkbox"/> No prenatal care <input type="checkbox"/> Birthing person known to be HIV-negative during pregnancy <input type="checkbox"/> Unknown			
<input type="checkbox"/> HIV serostatus of birthing person unknown <input type="checkbox"/> Other (specify) _____			
<b>Did birthing person receive any ARVs during labor/delivery?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown			
Date began ____ / ____ / ____ Date of last use ____ / ____ / ____			
<b>If YES, specify all ARVs</b>			
<b>If NO, select reason</b> <input type="checkbox"/> Precipitous delivery/STAT Cesarean delivery <input type="checkbox"/> HIV serostatus of birthing person unknown <input type="checkbox"/> Birth not in hospital			
<input type="checkbox"/> Birthing person tested HIV negative during pregnancy <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Unknown			
<b>Was the birthing person screened for any of the following conditions during this pregnancy?</b>			
<b>Check test(s) performed before birth</b>			
	<b>Yes</b>	<b>Date of screen (mm/dd/yyyy)</b>	<b>No</b>
			<b>Unknown</b>
Group B strep	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Hepatitis B (HBsAg)	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Rubella	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Syphilis	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
<b>Were any of the following conditions diagnosed for the birthing person during this pregnancy or at the time of labor and delivery?</b>			
	<b>Yes</b>	<b>Date of diagnosis (mm/dd/yyyy)</b>	<b>No</b>
			<b>Unknown</b>
Bacterial vaginosis	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
<i>Chlamydia trachomatis</i> infection	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Genital herpes	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Gonorrhea	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Group B strep	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Hepatitis B (HBsAg)	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Hepatitis C	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
PID	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Syphilis	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
Trichomoniasis	<input type="checkbox"/>	____ / ____ / ____	<input type="checkbox"/>
<b>Were substances used by the birthing person during this pregnancy?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
	<b>Used and injected</b>	<b>Used and did not inject</b>	<b>Used and unknown if injected</b>
			<b>Did not use</b>
			<b>Unknown if used</b>
Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crack cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fentanyl	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hallucinogens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heroin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
K2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (cannabis, THC, cannabinoids)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine (any tobacco)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specific drug(s) not documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**XI. Birthing Person History (for patients exposed perinatally with or without consequent infection) (cont)**

Was a toxicology screen done on the birthing person (either during this pregnancy or at the time of delivery)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If screening for the same substance was done on more than one occasion, record additional dates and results in Comments)					
	Not screened	Date of screen	Positive	Negative	Unknown
Alcohol	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamines	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturates	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crack cocaine	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fentanyl	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hallucinogens	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heroin	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
K2	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (cannabis, THC, cannabinoids)	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamines	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine (any tobacco)	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCP	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify) _____	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specific drug(s) not documented	<input type="checkbox"/>	___/___/___	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**XII. Treatment/Services Referrals (record all dates as mm/dd/yyyy)**

Has this child ever taken any ARVs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown									
ARV medication	Reason for use						Date began	Date of last use	
	HIV Tx	PrEP	PEP	PMTCT	HBV Tx	Other (specify reason)			
i. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
ii. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
iii. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
iv. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
v. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
(Record additional ARV medications in Comments)									
Has this child ever taken PCP prophylaxis <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Date began ___/___/___ Date of last use ___/___/___									
This child's primary caretaker is <input type="checkbox"/> 1—Biological parent <input type="checkbox"/> 2—Other relative <input type="checkbox"/> 3—Foster/Adoptive parent, relative <input type="checkbox"/> 4—Foster/Adoptive parent, unrelated <input type="checkbox"/> 7—Social service agency <input type="checkbox"/> 8—Other (specify in comments) <input type="checkbox"/> 9—Unknown									

**XIII. Comments**


**XIV. \*Local/Optional Fields**


## **National HIV Surveillance System (NHSS)**

Attachment 3(c)

Data Elements for the National HIV Surveillance System (NHSS)

## Data Elements for the National HIV Surveillance System (NHSS)

### Data Elements for Adult HIV I Case Reports

*Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0573)*

### Data Elements for Pediatric HIV Case Reports

*Public reporting burden of this collection of information is estimated to average 35 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0573)*

### Data Elements for Investigation Reporting and Evaluation

*Public reporting burden of this collection of information is estimated to average 1 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0573)*

The data elements listed below include data elements for adult/adolescent case reports (ACRF), pediatric case reports (PCRF), HIV incidence surveillance information (no longer collected), laboratory test data, investigation reporting and evaluation information and supplemental data collected from other document types such as birth certificates (BC), and death certificates (DEATH\_DOC). Data are stored in tables in the enhanced HIV Reporting System (eHARS). Information in the table below reflects information in the version of eHARS currently in place, v4.12, along with proposed changes to be implemented in eHARS v4.13 in 2023. The column "Transfer to CDC" indicates whether or not the data collected in a variable are transmitted to CDC. The column "Required/Optional" indicates whether a variable is: (1) a program requirement for collection (Required); (2) optional for program collection (Optional), which may include variables that are CDC recommended for collection but collection is optional; (3) generated by the eHARS system from entered values of other variables and is optional to collect (Optional-System); (4) generated by the eHARS system (System); (5) retired

from collection in eHARS (Retired); (6) retained from the previous case surveillance system and is not collected in eHARS (Legacy HARS); or (7) retained from the previous incidence surveillance system and is not collected in eHARS (Legacy Incidence). Additional information for users can be found in the eHARS 4.12 Technical Reference Guide for variables in the current version of eHARS; additional information about proposed changes to be implemented in eHARS v4.13 can be found in the Summary of Proposed Changes document.

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>ADDRESS</b>	<b>A table that maintains information on a person's addresses and locations.</b>				
address_dt	The most recent date for which this address is active.	YYYYMMDD	YES	ACRF, PCRF	Required
address_seq	Used by the system as a sequence identifier for a person's addresses.		YES	All	System
address_type_cd	A code indicating the type of address, such as RES (residential) or RSA (residence at AIDS diagnosis).	BAD - Bad address COR - Correctional facility CUR - Current FOS - Foster home HML - Homeless POS - Postal RAD - Residence at death RBI - Residence at birth RES - Residential RHE - Residence at perinatal exposure RSR - Residence at pediatric seroreversion RSA - Residence at diagnosis of stage 3 HIV infection (AIDS) RSH - Residence at diagnosis of HIV infection SHL - Shelter TMP – Temporary MIL – Military OTH - Other	YES	All	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
address_original_type_cd	Additional field for address type information when the address_type_cd captures an address event type.	BAD - Bad address COR - Correctional facility FOS - Foster home HML - Homeless POS - Postal RES - Residential SHL - Shelter TMP - Temporary MIL - Military OTH - Other	YES	All	Required
census_block_group	An optional field indicating the census block group for the person's address.		NO	ACRF, PCRF	Optional
census_congressional_district	An optional field indicating the congressional district for the person's address.		NO	ACRF, PCRF	Optional
census_group	An optional field indicating the census group for the person's address.		NO	ACRF, PCRF	Optional
census_msa	An optional field indicating the census metropolitan statistical area (MSA) for the person's address.		NO	ACRF, PCRF	Optional
census_tract	An optional field indicating the census tract for the person's address.		NO	ACRF, PCRF	Optional
city_fips	The city FIPS code for a person's address. (5 digits)	FIPS_CITY (table) - 99999	YES	All	Required
city_name	The textual city name for the person's address from the FIPS table. If there is no match to the FIPS table, the text is stored as entered by the user and preceded by an asterisk.	FIPS_CITY (table), ZIP_CITY (table)	YES	All	Required
country_cd	The ISO country code for a person's address.	COUNTRY_CODE (table)	YES	All	Required
country_usd	The FIPS U.S. dependency country code for the person's address.	COUNTRY_CODE (table)	YES	All	Required
county_fips	The FIPS county code for a person's address.	FIPS_COUNTY (table) - 999	YES	All	Required
county_name	The county name for the person's address from the FIPS table. If there is no match to the FIPS table, the text is	FIPS_COUNTY (table), ZIP_CITY (table)	YES	All	Required



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
	stored as entered by the user and preceded by an asterisk.				
doc_belongs_to	Indicates who the address data belong to: PERSON, MOTHER, or CHILD.	PERSON, MOTHER, CHILD	YES	All	System
document_uid	A unique identifier for a document.		YES	All	System
geographic_level	Geographic level to which the address was geocoded.	1=Street match 2=Zip code match 3=City and state match 4=No match	YES	All	Required
phone	The value indicating a person's telephone number.	9999999999	NO	All	Required
state_cd	The state postal code for a person's address.	STATE_CODES	YES	All	Required
street_address1	Primary description of a person's street address, such as number and street name.		NO	All	Required
street_address2	Secondary description of a person's street address, such as apartment, building, or unit and number.		NO	All	Required
zip_cd	The zip code associated with a person's address.	ZIP_CITY (table) - 99999	NO	All	Required
<b>ARV_PROPHYLAXIS</b>	<b>Maintains information on a person's antiretroviral drug and prophylaxis use.</b>				
document_uid	Identifies the document associated with each record stored on the table; document_uid is a unique value generated by eHARS to identify a document.		YES	ACRF, PCRF	System
drug_seq	Used by the system as a sequence identifier for each antiretroviral drug added to a document.		YES	ACRF, PCRF	System
obs_uid	An internal identifier for an observation.		YES	ACRF, PCRF	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
drug_cd	Identifier for an antiretroviral drug.	DRUG	YES	ACRF, PCRF	Optional
drug_rsn	Reason the person took the antiretroviral drug.	DRUG_RSN_CD	YES	ACRF, PCRF	Required
other_drug_rsn	Text entered to specify the reason the persons took the antiretroviral drug when a selection value is not available or appropriate.		YES	ACRF, PCRF	Required, if drug_rsn="OTH"
drug_start_dt	The date the person began taking the antiretroviral drug.	YYYYMMDD	YES	ACRF, PCRF	Required
drug_last_use_dt	The date the person last used the antiretroviral drug.	YYYYMMDD	YES	ACRF, PCRF	Required
other_drug_specify	Unlisted antiretroviral drug name.		YES	ACRF, PCRF	Optional
<b>BIRTH_DELIVERY</b>	<b>A table to capture final outcome of previous pregnancies of birthing person.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System
delivery_seq	Sequence number. Implement sequence number to way RISK and ADDRESS to handle all codes on PV.	0-999999	YES	PCRF, LEGACY_PEDIATRIC	System
csection_rsn_cd	A code to determine why the delivery was a C-section.	CESAREAN	YES	PCRF, LEGACY_PEDIATRIC	Optional
other_csection_rsnl	User entered detail regarding delivery.		YES	PCRF, LEGACY_PEDIATRIC	Optional
<b>BIRTH_HISTORY</b>	<b>A table that maintains information pertaining to the child's birth or the mother's prenatal care, labor, and delivery. This information is collected in the Birth History section of Pediatric Case Report Forms (PCRF) and Birth Certificate (BC) documents.</b>				
congenital_disorders	From PCRF, indicates the presence of birth defects.	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
congenital_disorders_cd	From PCRF and BC, birth defect codes.	01 - Anencephaly 02 - Meningomyelocele/Spina bifida 03 - Cyanotic congenital heart disease 04 - Congenital diaphragmatic hernia 05 - Omphalocele 06 - Gastroschisis 07 - Limb reduction defect (excluding congenital amputation and dwarfing syndromes) 08 - Cleft lip with or without cleft palate 09 - Cleft palate alone 10 - Down syndrome 11 - Suspected chromosomal disorder 12 - Down syndrome (karyotype confirmed) 13 - Suspected chromosomal disorder (karyotype confirmed) 14 - Down syndrome (karyotype pending) 15 - Suspected chromosomal disorder (karyotype pending) 16 - Hypospadias 17 - None of the anomalies listed above	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
Birth_history_avail	Birth history available	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
birth_place	From BC, place of birth, such as home or hospital	1 - Hospital 2 - Freestanding birthing center 3 - Home birth, Clinic/Doctor's office 9 - Unknown	YES	BC	Optional
birth_type	From PCRF and BC, the type of birth, such as single or twin.	1 - Single 2 - Twin 3 - >2 9 - Unknown	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
birth_wt	From PCRF and BC, the child's birth weight in grams.	NULL, MIN = 28, MAX = 9070	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
breastfed	From PCRF and BC: Was this child breastfed?	YES_NO_UNK	YES	BC	Optional
delivery_dt	Date when birthing person delivered infant(s).	YYYYMMDD	YES	PCRF, LEGACY_PEDIATRIC	Optional
delivery_method	From PCRF and BC, the method of delivery, such as vaginal or Cesarean.	DELIVERY, DELIVERY_BC	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
delivery_time	Military time when birthing person delivered infant(s).	HH:MM:SS	YES	PCRF, LEGACY_PEDIATRIC	Optional
document_uid	A unique identifier for the PCRF or BC.		YES	All	System
infant_transfer	From BC: Was the infant transferred to another facility?	YES_NO	YES	BC	Optional
neonatal_status	From PCRF, the child's neonatal status.	1 - Full Term 2 - Premature 9 - Unknown	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
neonatal_status_weeks	From PCRF and BC, the gestational age of the child at delivery.	01 - 98, 99(unknown), 00(none)	YES	PCRF, LEGACY_PEDIATRIC, BC	Optional
rupture_dt	Date when membrane rupture occurred.	YYYYMMDD	YES	PCRF, LEGACY_PEDIATRIC	Optional
rupture_time	Military time when membrane rupture occurred.	HH:MM:SS	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>BIRTHING_PERSON_HISTORY</b>	<b>A table that maintains information pertaining to the birthing person's prenatal care, labor, and delivery. This information is collected in the Birthing Person History section of Pediatric Case Report Forms (PCRF) documents.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System
first_onc_visit_dt	From BC, the date of birthing person's first prenatal care visit	YYYYMMDD	YES	BC	Optional
last_pnc_visit_dt	From BC, the date of the birthing person's last prenatal care visit	YYYYMMDD	YES	BC	Optional
last_normal_menses_dt	From BC, the date of the birthing person's last prenatal care visit.	YYYYMMDD	YES	BC	Optional
month_preg_pnc	From PCRF, the month of pregnancy that birthing person's prenatal care began.	01 - 10, 99(unknown), 00(none) 1-9 are stored with leading zero.	YES	PCRF, LEGACY_PEDIATRIC	Optional
num_pnc_visits	From PCRF and BC, the number of prenatal care visits.	01-98, 99(unknown), 00(none) 1-9 are stored with leading zero.	YES	PCRF, LEGACY_PEDIATRIC	Optional
preg_before	Has the birthing person been pregnant before.	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
num_prev_preg	Total number of previous pregnancies	1-30	YES	PCRF, LEGACY_PEDIATRIC	Optional
num_prev_live_births	Number of previous live births	1-30	YES	BC	Optional
bp_cd4_test	Test result (with a specimen collection date withing 6 weeks on or before delivery)	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional
Bp_first_post_dt	Date of birthing person's first HIV positive test result	YYMMDD	YES	ACRF, PCRF, LEGACY ACRF, LEGACY PCRF, DEATH, LAB	Optional
bp_vl_test	Test result (with a specimen collection date withing 6 weeks on or before delivery)	YES_NO_UNK	YES	PCRF, LEGACY_PEDIATRIC	Optional
<b>CALC_OBSERVATION</b>	<b>A table that maintains information on a person's calculated observations.</b>				
calc_obs_uid	A unique identifier for a calculated observation.	CALC_OBSERVATION_CODE (table)	YES	All	Refer to CALC_OBSERVATION_C ODE table for requirements for each variable
calc_obs_value	The calculated observation's value.		YES	All	Refer to CALC_OBSERVATION_C ODE table for valid data element values for each variable
document_uid	A unique identifier for a document.		YES	All	System
<b>CALC_OBSERVATION_CO DE</b>	<b>A table that maintains information calc_obs_value and associated descriptions.</b>				
1	HARS Legacy - AIDS category	1 - Definitive (pre-85) case 2 - Definitive (1985) case 3 - Definitive (1987) case 4 - Presumptive (1987) case	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		5 - Definitive (1993) case 6 - Presumptive (1993) case 7 - Immunologic (1993) case 8 - Undetermined case 9 - Non-case			
2	HARS Legacy - HIV category	1 - HIV Definitive 2 - HIV Presumptive 3 - HIV Indeterminate 4 - HIV Negative Definitive 5 - HIV Negative Presumptive 8 - Pending Confirmation 9 - HIV Unknown	YES	All	System
3	HARS Legacy - Date the first disease was diagnosed based on the 1993 expanded AIDS case definition	YES_NO	YES	All	System
4	HARS Legacy - Date the first disease was diagnosed based on the pre-1993 expanded AIDS case definition	YYYYMMDD	YES	All	System
5	HARS Legacy - Date of the first condition classifying as AIDS based on the current AIDS case definition	YYYYMMDD	YES	All	System
6	HARS Legacy - Date of the first condition classifying as AIDS based on the applicable AIDS case definition	YYYYMMDD	YES	All	System
7	HARS Legacy - Date of last negative HIV test result	YYYYMMDD	YES	All	System
8	HARS Legacy - Date a case was reported as HIV positive	YYYYMMDD	YES	All	System
9	HARS Legacy - Date a case was reported as AIDS category level 1	YYYYMMDD	YES	All	System
10	HARS Legacy - Date a case was reported as AIDS category level 2	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
11	HARS Legacy - Date a case was reported as AIDS category level 3	YYYYMMDD	YES	All	System
12	HARS Legacy - Date a case was reported as AIDS category level 4	YYYYMMDD	YES	All	System
13	HARS Legacy - Date a case was reported as AIDS category level 5	YYYYMMDD	YES	All	System
14	HARS Legacy - Date a case was reported as AIDS category level 6	YYYYMMDD	YES	All	System
15	HARS Legacy - Date a case was reported as AIDS category level 7	YYYYMMDD	YES	All	System
16	HARS Legacy - Date a case was reported as not infected with HIV	YYYYMMDD	YES	All	System
17	HARS Legacy - Date a case was reported as perinatal exposure	YYYYMMDD	YES	All	System
18	HARS Legacy - Date the death of a case was reported	YYYYMMDD	YES	All	System
19	HARS Legacy - Mode of transmission	01 - Male sexual contact with other male (MSM) 02 - Injection drug use (nonprescription) (IDU) 03 - Male sexual contact with other male and injection drug use (MSM & IDU) 04 - Adult received clotting factor for hemophilia/coagulation disorder 05 - Heterosexual contact 06 - Adult received transfusion of blood/blood components, transplant of organ/tissue, or artificial insemination 08 - Adult with other confirmed risk 09 - Adult with risk not reported/other	YES	All	System



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		11 - Child received clotting factor for hemophilia/coagulation disorder 12 - Mother with, or at risk for, HIV infection 13 - Child received transfusion of blood/blood components or transplant of organ/tissue 14 - Child with other risk 18 - Child with other confirmed risk 19 - Child with risk not reported/other			
20	HARS Legacy - Class	A1 - Asymptomatic, CD4 count > 500 or percent > 29% A2 - Asymptomatic, CD4 count 200-499 or percent 14-28% A3 - Asymptomatic, CD4 count < 200 or percent < 14% A9 - Asymptomatic, unknown CD4 B1 - Symptomatic, CD4 count > 500 or percent > 29% B2 - Symptomatic, CD4 count 200-499 or percent 14-28% B3 - Symptomatic, CD4 count < 200 or percent < 14%	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		B9 - Symptomatic, unknown CD4 C1 - AIDS, CD4 count > 500 or percent > 29% C2 - AIDS, CD4 count 200- 499 or percent 14-28% C3 - AIDS, CD4 count < 200 or percent < 14% C9 - AIDS, unknown CD4 Unknown clinical category, X1 - CD4 count > 500 or percent > 29% X2 - Unknown clinical category, CD4 count 200- 499 or percent 14-28% X3 - Unknown clinical category, CD4 count < 200 or percent < 14% X9 - Unknown clinical category, unknown CD4			
21	HARS Legacy - Date of first positive HIV test result or doctor diagnosis of HIV	YYYYMMDD	YES	All	System
78	HARS Legacy - CD4 count < 400	YES_NO	YES	All	System
85	HARS Legacy - First positive HIV-1 EIA test result date	YYYYMMDD	YES	All	System
86	HARS Legacy - Last negative HIV-1 EIA test result date	YYYYMMDD	YES	All	System
87	HARS Legacy - Most recent HIV-1 EIA test result value	POS=Positive NEG=Negative	YES	All	System
89	HARS Legacy - Most recent HIV-1 EIA test result date		YES	All	System
90	HARS Legacy - Overall HIV-1 EIA test result value	POS=Positive NEG=Negative	YES	All	System
91	HARS Legacy - Overall HIV-1 EIA test result date	YYYYMMDD	YES	All	System
92	HARS Legacy - First positive HIV-1/2 combined test result date	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
93	HARS Legacy - Last negative HIV-1/2 combined test result date	YYYYMMDD	YES	All	System
94	HARS Legacy - Most recent HIV-1/2 combined test result value	POS=Positive NEG=Negative	YES	All	System
95	HARS Legacy - Most recent HIV-1/2 combined test result date	YYYYMMDD	YES	All	System
96	HARS Legacy - Overall HIV-1/2 combined test result value	POS=Positive NEG=Negative	YES	All	System
97	HARS Legacy - Overall HIV-1/2 combined test result date	YYYYMMDD	YES	All	System
98	HARS Legacy - First positive Western Blot/IFA test result date	YYYYMMDD	YES	All	System
99	HARS Legacy - Last negative Western Blot/IFA test result date	YYYYMMDD	YES	All	System
100	HARS Legacy - Most recent Western Blot/IFA test result value	POS_NEG_IND	YES	All	System
101	HARS Legacy - Most recent Western Blot/IFA test result date	YYYYMMDD	YES	All	System
102	HARS Legacy - Overall Western Blot/IFA test result value	POS_NEG_IND	YES	All	System
103	HARS Legacy - Overall Western Blot/IFA test result date	YYYYMMDD	YES	All	System
104	HARS Legacy - First positive Other HIV Antibody test result date	YYYYMMDD	YES	All	System
105	HARS Legacy - Last negative Other HIV Antibody test result date	YYYYMMDD	YES	All	System
106	HARS Legacy - Most recent Other HIV Antibody test result value	POS_NEG_IND	YES	All	System
107	HARS Legacy - Most recent Other HIV Antibody test result date	YYYYMMDD	YES	All	System
108	HARS Legacy - Overall Other HIV Antibody test result value	POS_NEG_IND	YES	All	System
109	HARS Legacy - Overall Other HIV Antibody test result date	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
110	HARS Legacy - First positive Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
111	HARS Legacy - Last negative Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
112	HARS Legacy - Most recent Detection/Antigen/Viral load test result value	POS_NEG_IND	YES	All	System
113	HARS Legacy - Most recent Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
114	HARS Legacy - Overall Detection/Antigen/Viral load test result value	POS_NEG_IND	YES	All	System
115	HARS Legacy - Overall Detection/Antigen/Viral load test result date	YYYYMMDD	YES	All	System
116	HARS Legacy - Most recent CD4 count value		YES	All	System
117	HARS Legacy - Most recent CD4 percent value		YES	All	System
118	HARS Legacy - Most recent CD4 test result date	YYYYMMDD	YES	All	System
119	HARS Legacy - Lowest count from all CD4 test result values		YES	All	System
120	HARS Legacy - Lowest CD4 count test result date	YYYYMMDD	YES	All	System
121	HARS Legacy - Lowest percent from all CD4 test result values		YES	All	System
122	HARS Legacy - Lowest CD4 percent test result date	YYYYMMDD	YES	All	System
123	HARS Legacy - First CD4 count < 200 value		YES	All	System
124	HARS Legacy - First CD4 percent < 14 value		YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
125	HARS Legacy - First CD4 count < 200 or percent < 14 date	YYYYMMDD	YES	All	System
216	HARS Legacy - Expanded mode of transmission	01 - Male sexual contact with other male (MSM) 02 - Injection drug use (nonprescription) (IDU) 03 - Male sexual contact with other male and injection drug use (MSM & IDU) 04 - Adult received clotting factor for hemophilia/coagulation disorder 05 - Heterosexual contact with injection drug user 06 - Heterosexual contact with bisexual man 07 - Heterosexual contact with person with hemophilia 08 - Born in an NIR country Heterosexual contact with person born in an NIR country 09 - Heterosexual contact with HIV-infected transfusion recipient 11 - Heterosexual contact with HIV-infected person 12 - Heterosexual contact with person at risk for HIV infection 13 - Adult received transfusion of blood/blood	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		components, transplant of organ/tissue, or artificial insemination 14 - Adult with risk not reported/other 15 - Child received clotting factor for hemophilia/coagulation disorder 16 - Mother injection drug use (nonprescription) (IDU) 17 - Mother had sex with male injection drug user 18 - Mother had sex with bisexual man 19 - Mother had sex with person with hemophilia 20 - Mother born in an NIR country 21 - Mother had sex with person born in an NIR country 22 - Mother had sex with HIV-infected transfusion recipient 23 - Mother had sex with HIV-infected man 24 - Mother received transfusion of blood/blood components, transplant of organ/tissue, or artificial insemination 25 - Mother has HIV infection 26 - Child received transfusion of blood/blood components or transplant of organ/tissue			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		27 - Child with risk not reported/other 28 - Child with other risk 88 - Child with other confirmed risk			
217	Old race	1 - White, not Hispanic 2 - Black, not Hispanic 3 - Hispanic 4 - Asian/Pacific Islander 5 - American Indian/Alaska Native 9 - Unknown	YES	All	System
218	Race	1 - Hispanic, All races 2 - Not Hispanic, American Indian/Alaska Native 3 - Not Hispanic, Asian 4 - Not Hispanic, Black 5 - Not Hispanic, Native Hawaiian/Pacific Islander 6 - Not Hispanic, White 7 - Not Hispanic, Legacy Asian/Pacific Islander 8 - Not Hispanic, Multi-race 9 - Unknown	YES	All	System
219	Earliest date the first document was entered into the system	YYYYMMDD	YES	All	System
220	Earliest date the first document was received at the health department	YYYYMMDD	YES	All	System
221	Transmission category	01 - Male sexual contact with other male (MSM) 02 - Injection drug use (nonprescription) (IDU) 03 - Male sexual contact with other male and	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		injection drug use (MSM+IDU) 04 - Adult received clotting factor for hemophilia/coagulation disorder 05 - Heterosexual contact 06 - Adult received transfusion of blood/blood components, transplant of organ/tissue, or artificial insemination 07 - Perinatal exposure with HIV infection first diagnosed at age 13 years or older 08 - Adult with other confirmed risk 09 - Adult with No Identified Risk (NIR) 10 - Adult with No Reported Risk (NRR) 11 - Child received clotting factor for hemophilia/coagulation disorder 12 - Perinatal exposure 13 - Child received transfusion of blood/blood components or transplant of organ/tissue 18 - Child with other confirmed risk 19 - Child with No Identified Risk (NIR) 20 - Child with No Reported Risk (NRR)			



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		99 - Risk factors selected with no age at diagnosis			
222	Expanded transmission category	01-Adult male sexual contact with male (MSM) 02-Adult injection drug use (IDU) 03-Adult MSM & IDU 04-Adult received clotting factor 05-Adult heterosexual contact with IDU 06-Adult heterosexual contact with bisexual male 07-Adult heterosexual contact with person with hemophilia or coagulation disorder 10-Adult heterosexual contact with transfusion or transplant recipient with documented HIV infection 11-Adult heterosexual contact with person with documented HIV infection, risk factor not specified 13-Adult received transfusion or transplant 14-Adult undetermined transmission category 15-Child received clotting factor 16-Mother IDU 17-Mother had heterosexual contact with IDU	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		18-Mother had heterosexual contact with bisexual male 19-Mother had heterosexual contact with person with hemophilia or coagulation disorder 22-Mother had heterosexual contact with transfusion or transplant recipient with documented HIV infection 23-Mother had heterosexual contact with person with documented HIV infection, risk factor not specified 24-Mother received transfusion or transplant 25-Mother HIV positive 26-Child received transfusion or transplant 27-Child undetermined transmission category 28-Child other confirmed risk factor 88-Adult other confirmed risk factor 99-Adult and pediatric risk factors selected with no age at diagnosis  f			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
223	Exposure category	01 - MSM only 02 - IDU only 03 - Heterosexual contact only 04 - MSM & IDU 05 - IDU & Heterosexual contact 06 - MSM & Heterosexual contact 07 - MSM & IDU & Heterosexual contact 08 - Perinatal exposure 09 - Other 10 - No Identified Risk (NIR) 11 - No Reported Risk (NRR) 99-Adult and pediatric risk factors selected with no age at diagnosis	YES	All	System
224	Date of first positive HIV test result or doctor diagnosis of HIV	YYYYMMDD	YES	All	System
225	Type of first evidence of HIV infection (positive HIV test result or doctor diagnosis of HIV)	1 - Lab test 2 - Physician diagnosis	YES	All	System
226	First CD4 or viral load test result date after HIV diagnosis	YYYYMMDD	YES	All	System
227	Type of first test after HIV diagnosis (CD4 or viral load)	1 - CD4 2 - Viral load 3 - CD4 and Viral Load	YES	All	System
228	Most recent test result date	YYYYMMDD	YES	All	System
229	Most recent test type	1 - CD4 2 - Viral load	YES	All	System
230	Most recent test result value	LAB_RESULT_VALUE	YES	All	System
243	First detectable viral load test result date	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
244	First detectable viral load test result value (copies/ml)		YES	All	System
245	Most recent viral load test result value (copies/ml)		YES	All	System
246	Most recent viral load test result date	YYYYMMDD	YES	All	System
247	Most recent undetectable viral load test result date	YYYYMMDD	YES	All	System
252	The earliest date on which the immunologic criteria for stage 3 were met	YYYYMMDD	YES	All	System
253	First CD4 count test result < 350 value		YES	All	System
254	First CD4 count test result < 350 date	YYYYMMDD	YES	All	System
255	Most recent CD4 count test result value		YES	All	System
256	Most recent CD4 count test result date	YYYYMMDD	YES	All	System
257	Most recent CD4 percent test result value		YES	All	System
258	Most recent CD4 percent test result date	YYYYMMDD	YES	All	System
259	Most recent CD4 test result (count or percent) date	YYYYMMDD	YES	All	System
260	First CD4 test result value after HIV diagnosis		YES	All	System
261	First CD4 test result date after HIV diagnosis	YYYYMMDD	YES	All	System
262	Lowest CD4 count test result value		YES	All	System
263	Lowest CD4 count test result date	YYYYMMDD	YES	All	System
264	Lowest CD4 percent test result value		YES	All	System
265	Lowest CD4 percent test result date	YYYYMMDD	YES	All	System
266	First positive Qualitative RNA/DNA test result date	YYYYMMDD	YES	All	System
267	Most recent Qualitative RNA/DNA test result value		YES	All	System
268	Most recent Qualitative RNA/DNA test result date	YYYYMMDD	YES	All	System
269	Most recent negative Qualitative RNA/DNA Test Result date	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
270	First positive HIV antigen test result date	YYYYMMDD	YES	All	System
271	First positive HIV culture test result date	YYYYMMDD	YES	All	System
272	HIV case definition category	1 - HIV positive, definitive 2 - HIV positive, presumptive 3 - HIV indeterminate 4 - HIV negative, definitive 5 - HIV negative, presumptive 8 - Pending confirmation 9 - Unknown	YES	All	System
273	AIDS case definition category	7 - AIDS case defined by immunologic (CD4 count or percent) criteria 9 - Not an AIDS case A - AIDS case defined by clinical disease (OI) criteria	YES	All	System
274	Age at HIV diagnosis (years)	1-99	YES	All	System
275	Age at HIV diagnosis (months)	1-99	YES	All	System
276	Age at AIDS diagnosis (years)	1-99	YES	All	System
277	Age at AIDS diagnosis (months)	1-99	YES	All	System
278	Age at HIV disease diagnosis (years)	1-99	YES	All	System
279	Age at HIV disease diagnosis (months)	1-99	YES	All	System
281	Date of the earliest condition classifying the case as stage 3 HIV infection	YYYYMMDD	YES	All	System
282	The earliest date on which the clinical disease criterion (opportunistic illness [OI] diagnosis) for stage 3 HIV infection was met	YYYYMMDD	YES	All	System
285	HIV disease diagnosis date	YYYYMMDD	YES	All	System
287	Diagnostic status	1 - Adult HIV 2 - Adult AIDS 3 - Perinatal HIV exposure	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		4 - Pediatric HIV 5 - Pediatric AIDS 6 - Pediatric seroreverter 9 - Unknown			
288	Date reported as HIV positive	YYYYMMDD	YES	All	System
289	Date reported as not infected with HIV (seroreverters)	YYYYMMDD	YES	All	System
290	Date reported as perinatal exposure	YYYYMMDD	YES	All	System
291	Date reported as AIDS (non- immunologic)	YYYYMMDD	YES	All	System
292	Date reported as AIDS (immunologic)	YYYYMMDD	YES	All	System
293	Date reported as AIDS (earliest)	YYYYMMDD	YES	All	System
294	Date reported as HIV disease	YYYYMMDD	YES	All	System
295	Disease progression category (report date)	YYYYMMDD	YES	All	System
296	Disease progression category (diagnosis date)	YYYYMMDD	YES	All	System
297	Meets CDC case definition for HIV (not AIDS)	YES_NO	YES	All	System
298	Meets CDC case definition for AIDS	YES_NO	YES	All	System
299	Meets CDC case definition for HIV disease	YES_NO	YES	All	System
300	Meets CDC eligibility for HIV (not AIDS)	YES_NO	YES	All	System
301	Meets CDC eligibility for AIDS	YES_NO	YES	All	System
302	Meets CDC eligibility for HIV disease	YES_NO	YES	All	System
303	Age at death (years)	1-99	YES	All	System
304	Age at death (months)	1-99	YES	All	System
305	Date death reported	YYYYMMDD	YES	All	System
306	Type of first CD4 test after HIV diagnosis (count or percent)	RESULT_UNITS_CD4	YES	All	System
307	Meets CDC case definition for HIV perinatal exposure or pediatric seroreverter	YES_NO	YES	All	System
308	Meets CDC eligibility for HIV perinatal exposure or pediatric seroreverter	YES_NO	YES	All	System
309	Laboratory documented date of last negative before first positive HIV test result	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
310	Date of last negative before first positive HIV test result from testing history	YYYYMMDD	YES	All	System
312	Stage 0 HIV infection at diagnosis	A – Stage 0, <b>acute</b> infection at diagnosis B – Stage 0, <b>unknown if acute</b> at diagnosis N – Insufficient evidence for diagnosis	YES	All	System
313	Stage at diagnosis based only on CD4 and opportunistic illness (OI)	1 - Stage 1, CD4 cnt≥500 or CD4 pct≥26 2 - Stage 2, 200≤CD4 cnt≤499 or 14≤CD4 pct≤25 3 - Stage 3, OI or CD4 cnt<200 or CD4 pct <14 9 - Stage unknown	YES	All	System
314	Date of earliest use of antiretroviral medications for HIV treatment	YYYYMMDD	YES	All	System
315	Date of last use of antiretroviral medications for HIV treatment	YYYYMMDD	YES	All	System
316	Date of earliest use of antiretroviral medications for pre-exposure prophylaxis	YYYYMMDD	YES	All	System
317	Date of last use of antiretroviral medications for pre-exposure prophylaxis	YYYYMMDD	YES	All	System
318	Date of earliest use of antiretroviral medications for post-exposure prophylaxis	YYYYMMDD	YES	All	System
319	Date of last use of antiretroviral medications for post-exposure prophylaxis	YYYYMMDD	YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
320	Date of earliest use of antiretroviral medications for prevention of mother-to-child transmission	YYYYMMDD	YES	All	System
321	Date of last use of antiretroviral medications for prevention of mother-to-child transmission	YYYYMMDD	YES	All	System
322	Date of earliest use of antiretroviral medications for Hepatitis B treatment	YYYYMMDD	YES	All	System
323	Date of last use of antiretroviral medications for Hepatitis B	YYYYMMDD	YES	All	System
324	Date of earliest use of antiretroviral medications for other reasons	YYYYMMDD	YES	All	System
325	Date of last use of antiretroviral medications for other reasons	YYYYMMDD	YES	All	System
326	Date of earliest use of antiretroviral medications	YYYYMMDD	YES	All	System
327	Date of last use of antiretroviral medications	YYYYMMDD	YES	All	System
328	Did mother receive any antiretroviral medications prior to this pregnancy?	YES, NO_REF_UNK	YES	All	System
329	Date of mother's earliest use of antiretroviral medications prior to this pregnancy	YYYYMMDD	YES	All	System
330	Date of mother's last use of antiretroviral medications prior to this pregnancy	YYYYMMDD	YES	All	System
331	Did mother receive any antiretroviral medications during pregnancy?	YES, NO_REF_UNK	YES	All	System
332	Date of mother's earliest use of antiretroviral medications during pregnancy	YYYYMMDD	YES	All	System
333	Date of mother's last use of antiretroviral medications during pregnancy	YYYYMMDD	YES	All	System
334	Did mother receive any antiretroviral medications during labor/delivery?	YES, NO_REF_UNK	YES	All	System



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
335	Date of mother's earliest use of antiretroviral medications during labor/delivery	YYYYMMDD	YES	All	System
336	Date of mother's last use of antiretroviral medications during labor/delivery	YYYYMMDD	YES	All	System
337	Ever transgender or additional gender identity	MF, FM, AD	YES	All	System
<b>CONSENT_QUESTIONNAIRE</b>	<b>A table that maintains information on a person's consent for STARHS.</b> <b>Note: All variables in this tables were not collected since 2005 but are stored in eHARS.</b>				
cconsent1	Did the person consent to participate in STARHS when approached the first time?	YES_NO_UNK	YES	LEGACY_CONSENT	Retired
cconsent2	Did the person consent to participate in STARHS when approached the second time?	YES_NO_UNK	YES	LEGACY_CONSENT	Retired
cconsentvisit1	The type of visit when the person was approached for STARHS consent the first time.	01 - Pre-test 02 - Post-test 03 - Other Follow-up	YES	LEGACY_CONSENT	Retired
cconsentvisit2	The type of visit when the person was approached for STARHS consent the second time.	01 - Pre-test 02 - Post-test 03 - Other Follow-up	YES	LEGACY_CONSENT	Retired
cdate1	Date of first approach for consent.	YYYYMMDD	YES	LEGACY_CONSENT	Retired
cdate2	Date of second approach for consent.	YYYYMMDD	YES	LEGACY_CONSENT	Retired
document_uid	A unique identifier for a document.		YES	LEGACY_CONSENT	System
<b>DEATH</b>	<b>A table that maintains information on a person's death.</b>				
autopsy	Was an autopsy performed?	YES_NO_UNK	YES	LEGACY_NDI, DEATH_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
city_fips	The FIPS code for the city where the person died.	FIPS_CITY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
city_name	The name of the city where the person died.	FIPS_CITY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
country_cd	The ISO code for the country where the person died.	COUNTRY_CODE (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
country_usd	The U.S. Dependency code where the person died.	COUNTRY_CODE (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
county_fips	The FIPS code for the county where the person died.	FIPS_COUNTY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
county_name	The name of the county where the person died.	FIPS_COUNTY (table)	YES	LEGACY_NDI, DEATH_DOC	Optional
document_uid	A unique identifier for the Death Document.		YES	ACRF, PCRF, DEATH_DOC, LEGACY_NDI, LEGACY_ADULT, LEGACY_PEDIATRIC	System
dod	The person's date of death.	YYYYMMDD	YES	ACRF, PCRF, DEATH_DOC, LEGACY_NDI, LEGACY_ADULT, LEGACY_PEDIATRIC	Required if person's vital status = Dead
place	The type of place where the person died, such as a residence or hospital.	1 - Hospital, inpatient 2 - Hospital, outpatient or emergency room 3 - Hospital, dead on arrival 4 - Nursing home or hospice 5 - Residence 6 - Jail/Adult detention center 7 - Juvenile detention center 8 - Group/Assisted living home	YES	DEATH_DOC, LEGACY_NDI,	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		9 - Homeless shelter 10 - Homeless, on the street 11 - Hospital, institution (HARS) 888 - Other 999 - Unknown			
state_cd	The postal code for the state where the person died.	STATE_CODES	YES	ACRF, PCRF, DEATH_DOC, LEGACY_NDI, LEGACY_ADULT, LEGACY_PEDIATRIC	Required if person's vital status = Dead
<b>DEATH_DX</b>	<b>A table that maintains information on a person's causes of death.</b>				
descr	A phrase or statement describing the cause of death.		YES	LEGACY_NDI, DEATH_DOC	Optional
document_uid	A unique identifier for the Death Document.		YES	LEGACY_NDI, DEATH_DOC	Optional
icd_cd	The ICD code assigned.	ICD9, ICD10	YES	LEGACY_NDI, DEATH_DOC	Optional
icd_cd_type	The type of ICD code assigned, either ICD 9 (represented by 9) or ICD 10 (represented by 10).	9 - ICD-9 10 - ICD-10	YES	LEGACY_NDI, DEATH_DOC	Optional
line	A system generated number for NCHS electronic data, the line number on the tape.	1-9	YES	LEGACY_NDI, DEATH_DOC	Optional
line_number	A number indicating the sequence of death causes (00 is first).	00-20	YES	LEGACY_NDI, DEATH_DOC	Optional
nature_of_injury	For NCHS electronic data, the nature of injury flag (1 represents nature of injury codes and 0 represents all other cause codes).	0,1	YES	LEGACY_NDI, DEATH_DOC	Optional
position	Corresponds to the position of the cause of death on each line of the death		YES	LEGACY_NDI, DEATH_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
	certificate (1 if the cause is the first one listed, 2 if the cause is the second one listed, and so forth).				
<b>DOCUMENT</b>	<b>A table that maintains information about a document (such as a case report form).</b>				
author	The person who completed the original form.		NO	All	Optional
author_phone	The phone number of the person who completed the original form.	7 or 10 digits	NO	All	Optional
complete_dt	Date the form or document was completed or populated with information. For example, when the chart abstraction was completed.	YYYYMMDD	YES	All	Required
document_number	A field indicating the number of the document. For example, the certificate number associated with a birth certificate.		NO	All	Optional
document_source_cd	The source code of the document, such as A01 for Inpatient Record or A02 for Outpatient Record.	A01.01-Inpatient Record/Acute Care Facility A01.01.01-Inpatient Record/Acute Care Facility/Infection Control Practitioner A01.01.02-Inpatient Record/Acute Care Facility/Obstetrics and Gynecology A01.01.02.01-Inpatient Record/Acute Care Facility/Obstetrics and Gynecology/Prenatal Care A01.01.02.02-Inpatient Record/Acute Care Facility/Obstetrics and Gynecology/Labor and Delivery	YES	All	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A01.01.03-Inpatient Record/Acute Care Facility/Pediatric A01.01.04-Inpatient Record/Acute Care Facility/Birth A01.01.05-Inpatient Record/Acute Care Facility/All Other A01.02-Inpatient Record/Veteran's Administration Hospital A01.02.01-Inpatient Record/Veteran's Administration Hospital/Infection Control Practitioner A01.02.02-Inpatient Record/Veteran's Administration Hospital/All Other A01.03-Inpatient Record/Military Hospital A01.03.01-Inpatient Record/Military Hospital/Infection Control Practitioner A01.03.02-Inpatient Record/Military Hospital/Obstetrics and Gynecology A01.03.02.01-Inpatient Record/Military Hospital/Obstetrics and Gynecology/Prenatal Care			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A01.03.02.02-Inpatient Record/Military Hospital/Obstetrics and Gynecology Labor and Delivery A01.03.03-Inpatient Record/Military Hospital/Pediatric A01.03.04-Inpatient Record/Military Hospital/All Other A01.04-Inpatient Record/Long Term Care Facility A01.04.01-Inpatient Record/Long Term Care Facility/Nursing Home A01.04.02-Inpatient Record/Long Term Care Facility/Rehabilitation Center An inpatient facility specifically designed to help restore normal function (to the extent possible) in an A01.04.03-Inpatient Record/Long Term Care Facility/Drug Treatment Program A01.05-Inpatient Record/Hospice A02-Outpatient Record A02.01-Outpatient Record/HMO A02.01.01-Outpatient Record/HMO/Hospital- associated outpatient clinic			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.01.02-Outpatient Record/HMO/Non- Hospital associated outpatient clinic A02.02-Outpatient Record/VA Outpatient Clinic A02.03-Outpatient Record/Private Physician A02.03.01-Outpatient Record/Private Physician/Hospital- associated outpatient clinic A02.03.02-Outpatient Record/Private Physician/Non-Hospital associated outpatient clinic A02.04-Outpatient Record/Adult HIV Clinic A02.04.01-Outpatient Record/Adult HIV Clinic/Hospital-associated outpatient clinic A02.04.02-Outpatient Record/Adult HIV Clinic/Non-Hospital associated outpatient clinic A02.05-Outpatient Record/Infectious Disease Clinic A02.05.01-Outpatient Record/Infectious Disease Clinic/Hospital- associated outpatient clinic A02.05.02-Outpatient Record/Infectious Disease			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		Clinic/Non-Hospital associated outpatient clinic A02.06-Outpatient Record/County Health Dept. Clinic A02.07-Outpatient Record/Maternal HIV Clinic A02.07.01-Outpatient Record/Maternal HIV Clinic/Hospital-associated outpatient clinic A02.07.02-Outpatient Record/Maternal HIV Clinic/Non-Hospital associated outpatient clinic A02.08-Outpatient Record/Prenatal Clinic A02.08.01-Outpatient Record/Prenatal Clinic/Hospital-associated outpatient clinic A02.08.02-Outpatient Record/Prenatal Clinic/Non-Hospital associated outpatient clinic A02.09-Outpatient Record/Pediatric HIV Clinic A02.09.01-Outpatient Record/Pediatric HIV Clinic/Hospital-associated outpatient clinic A02.09.02-Outpatient Record/Pediatric HIV Clinic/Non-Hospital associated outpatient clinic A02.10-Outpatient Record/Obstetrics and Gynecology			



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.10.01-Outpatient Record/Obstetrics and Gynecology/Hospital- associated outpatient clinic A02.10.02-Outpatient Record/Obstetrics and Gynecology/Non-Hospital associated outpatient clinic A02.11-Outpatient Record/Pediatric Clinic A02.11.01-Outpatient Record/Pediatric Clinic/Hospital-associated outpatient clinic A02.11.02-Outpatient Record/Pediatric Clinic/Non-Hospital associated outpatient clinic A02.12-Outpatient Record/TB Clinic A02.12.01-Outpatient Record/TB Clinic/Hospital- associated outpatient clinic A02.12.02-Outpatient Record/TB Clinic/Non- Hospital associated outpatient clinic A02.14-Outpatient Record/Indian Health Service Clinic A02.14.01-Outpatient Record/Indian Health Service Clinic/Hospital- associated outpatient clinic			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.14.02-Outpatient Record/Indian Health Service Clinic/Non- Hospital associated outpatient clinic A02.15-Outpatient Record/Early Intervention Nurse A02.15.01-Outpatient Record/Early Intervention Nurse/Hospital- associated outpatient clinic A02.15.02-Outpatient Record/Early Intervention Nurse/Non- Hospital associated outpatient clinic A02.16-Outpatient Record/Visiting Nurse Service A02.16.01-Outpatient Record/Visiting Nurse Service/Hospital- associated outpatient clinic A02.16.02-Outpatient Record/Visiting Nurse Service/Non-Hospital associated outpatient clinic A02.17-Outpatient Record/Hemophilia Treatment Center A02.17.01-Outpatient Record/Hemophilia Treatment Center/Hospital- associated outpatient clinic A02.17.02-Outpatient Record/Hemophilia Treatment Center/Non- Hospital associated outpatient clinic			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A02.18-Outpatient Record/Hospice A02.18.01-Outpatient Record/Hospice/Hospital- associated outpatient clinic A02.18.02-Outpatient Record/Hospice/Non- Hospital associated outpatient clinic A02.19-Outpatient Record/Drug Treatment Center A02.19.01-Outpatient Record/Drug Treatment Center/Hospital- associated outpatient clinic A02.19.02-Outpatient Record/Drug Treatment Center/Non- Hospital associated outpatient clinic A02.20-Outpatient Record/Rehabilitation Center A02.20.01-Outpatient Record/Rehabilitation Center/Hospital-associated outpatient clinic A02.20.02-Outpatient Record/Rehabilitation Center/Non-Hospital associated outpatient clinic A02.25-Outpatient Record/Other Clinic A02.25.01-Outpatient Record/Other			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		Clinic/Hospital-associated outpatient clinic A02.25.02-Outpatient Record/Other Clinic/Non- Hospital associated outpatient clinic A03-Emergency Room A04-Screening, Diagnosis and Referral Agency A04.01-Screening, Diagnosis and Referral Agency/Blood Bank A04.02-Screening, Diagnosis and Referral Agency/Drug Treatment Clinic or Program A04.03-Screening, Diagnosis and Referral Agency/Family Planning Clinic A04.04-Screening, Diagnosis and Referral Agency/HIV Case Management Agency A04.05-Screening, Diagnosis and Referral Agency/HIV Counseling and Testing Site A04.06-Screening, Diagnosis and Referral Agency/Immigration A04.07-Screening, Diagnosis and Referral Agency/Insurance Report A04.08-Screening, Diagnosis and Referral Agency/Job Corps			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A04.09-Screening, Diagnosis and Referral Agency/Military A04.10-Screening, Diagnosis and Referral Agency/Partner Counseling and Referral Services A04.11-Screening, Diagnosis and Referral Agency/STD Clinic A04.12-Public health notes A05-Laboratory A05.01-Laboratory/Hospital A05.02-Laboratory/State A05.03-Laboratory/Private A05.03.01- Laboratory/Private/Referen ce A05.03.02- Laboratory/Private/Other A06-Other Database A06.01-Other Database/AIDS Drug Assistance Program (ADAP) A06.02-Other Database/ASD A06.03-Other Database/Birth Certificate A06.04-Other Database/Birth Defects Registry A06.05-Other Database/Cancer Registry A06.06-Other Database/Database			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		provided by coroner not associated with inpatient facility A06.07-Other Database/Death Certificate A06.08-Other Database/EHRAP A06.09-Other Database/EPS A06.10-Other Database/HARS A06.11-Other Database/Health department records A06.12-Other Database/Hepatitis Registry A06.13-Other Database/Hospital billing summary or discharge records A06.14-Other Database/HRSA HIV CARE A06.15-Other Database/Immunization registry A06.16-Other Database/Medicaid Records A06.17-Other Database/National Death Index (NDI) Search A06.18-Other Database/Out of State Reports A06.19-Other Database/Prison, Jail or Other Correctional Facility			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A06.20-Other Database/PSD A06.21-Other Database/State Disease Registry A06.22-Other Database/SHAS A06.23-Other Database/SHDC A06.24-Other Database/STD Registry A06.25-Other Database/Tuberculosis Registry A06.27-Other Database/Vital Statistics (State/Local) A06.28-Other Database/HARS NDI A06.29-Other Database/RIDR A06.29.01-Other Database/RIDR/CDC RIDR A06.29.02-Other Database/RIDR/CDC Soundex Check A06.29.03-Other Database/RIDR/Other State-to-State Communications A06.30-Other Database/SSDMF or SSDI A06.31-Other Database/Legacy TTH Pre- test			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		A06.32-Other Database/Legacy TTH Post- test A06.33-Other Database/Legacy Consent A06.34-Other Database/MMP A06.34.01-Other Database/MMP/Medical Record Abstraction A06.34.02-Other Database/MMP/Patient Interview A06.35-Other Database/FIMR A06.35.01-Other Database/FIMR/Medical Record Abstraction A06.35.02-Other Database/FIMR/Patient Interview A06.36-Other Database/Internet Person/People Search A06.50-Other Database/Other A07-Other Facility Record A07.01-Other Facility Record/Prison, jail, or other correctional facility A07.02-Other Facility Record/Coroner not associated with inpatient facility A10-Other source A10.01-COPHI Investigation A10.02-Patient interview UNK-Unknown			



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		SOURCE-No source defined			
document_type_cd	A code indicating the type of document, such as 001 for Adult Case Report Form or 005 for Birth Certificate.	000-document.personView 001- document.adultCaseReport Doc 002- document.pediatricReportD oc 003- document.harsAdultDoc 004-document.lab 005- document.birthCertificated oc 006- document.deathCertificate Doc 009document.harsPediatric Doc 010-Supplemental Risk Form 011-document.harsNdiDoc 012-document.tthDoc 013-document.consent  15 - document.starhs	YES	All	System
document_uid	A unique identifier for a document.		YES	All	System
ehars_uid	A unique identifier for a case or person.		YES	All	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
enter_by	The user ID of the person who entered the information into eHARS, auto-populated by the application.		NO	All	Optional
enter_dt	The system date when the document was entered into eHARS.	YYYYMMDD	YES	All	System
facility_uid	Indicates the facility completing the form.	FACILITY_CODE (table)	YES	ACRF, PCRF, LEGACY_CONSENT, LEGACY_TTH	Optional - System
initdocuid	If this document contains follow up information, this field captures the document UID of the report that initiated the investigation.		YES	All	Required if follow-up document
initinvest	Did this document initiate a follow-up investigation?	YES_NO_UNK	YES	All	Optional
modify_dt	The date the document was last modified.	YYYYMMDD	YES	All	Optional
notes	Notes or comments regarding the document.		NO	All	Optional
provider_uid	Indicates the provider completing the form.	PROVIDER_CODE (table)	NO	ACRF, PCRF, LEGACY_CONSENT, LEGACY_TTH	Optional - System
pv_categ	The Person View AIDS category at the time the document was entered into eHARS. <b>(Note: This field was retired from usage as of version 4.0)</b>		YES	All	System
pv_hcateg	The Person View HIV category at the time the document was entered into the system. <b>(Note: This field was retired from usage as of version 4.0)</b>		YES	All	System
receive_dt	The date the document was received at the health department.	YYYYMMDD	YES	All	Optional
rep_hlth_dept_cd	The health department reporting this information to the site. The code consists of the state abbreviation and either the three-digit FIPS county code (state + fips county code), or the five-digit FIPS place code (state + fips place code).	Two-character state abbreviation + three-digit FIPS county code or five-digit FIPS place code	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
rep_hlth_dept_name	The name of the reporting health department.		YES	All	Required
rpt_medium	An indication of the medium used to transport the information to the site, such as paper form, faxed or diskette, mailed.	1 - Paper form, field visit 2 - Paper form, mailed 3 - Paper form, faxed 4 - Telephone 5 - Electronic transfer, Internet 6 - Diskette, mailed	YES	All	Optional
ship_flag	A value indicating if the document/Person View needs to be transferred to state health department (satellite installations) or to CDC.	0-9999	YES	All	System
site_cd	A unique identifier representing the reporting site or location where eHARS is installed.	SITE_CODE	YES	All	System
status_flag	A value indicating the status of the document or Person View.	DOCUMENT_STATUS (non-pv documents), PERSON_VIEW_STATUS (pv documents)	YES	All	System
surv_method	A field indicating whether the report was obtained via active or passive surveillance.	A - Active F - Follow-up P - Passive R - Reabstraction U - Unknown	YES	All	Required
<b>FACILITY_CODE</b>	<b>A table that maintains information for selecting and identifying healthcare facilities.</b>				
city_fips	City FIPS code for the facility's address.	FIPS_CITY (table)	YES	N/A	Optional
city_name	City name associated with the facility's address.	FIPS_CITY (table)	YES	N/A	Optional
country_cd	ISO country code for the facility's address.	COUNTRY_CODE (table)	YES	N/A	Optional
country_usd	U.S. dependency code for the facility's address, if applicable.	COUNTRY_CODE (table)	YES	N/A	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
county_fips	County FIPS code for the facility's address.	FIPS_COUNTY (table)	YES	N/A	Optional
county_name	County name associated with the facility's address.	FIPS_COUNTY (table)	YES	N/A	Optional
email	The email address of the facility.		NO	N/A	Optional
facility_type_cd	A code indicating the type of healthcare facility.	F.OTH-Facility/Other F.UNK-Facility/Unknown F01-Inpatient Facility F01.01-Inpatient Facility/Hospital F01.04-Inpatient Facility/Long Term Care F01.50-Inpatient Facility/Drug Treatment F01.OTH-Inpatient Facility/Other F01.UNK-Inpatient Facility/Unknown F02-Outpatient Facility F02.01-Outpatient Facility/HMO Clinic F02.03-Outpatient Facility/Private Physician's Office F02.04-Outpatient Facility/Adult HIV Clinic F02.05-Outpatient Facility/Infectious Disease Clinic F02.09-Outpatient Facility/Pediatric HIV Specialty Clinic F02.10-Outpatient Facility/Obstetrics and Gynecology Clinic F02.11-Outpatient Facility/Pediatric Clinic	YES	N/A	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		F02.12-Outpatient Facility/TB Clinic F02.16-Outpatient Facility/Home Health Agency F02.17-Outpatient Facility/Hemophilia Treatment Center F02.18-Outpatient Facility/Hospice F02.19-Outpatient Facility/Drug Treatment Center F02.25-Outpatient Facility/Other Clinic F02.50-Outpatient Facility/ACTG Site F02.51-Outpatient Facility/Community Health Center F02.52-Outpatient Facility/Employee Health Clinic F02.53-Outpatient Facility/Health Department/Public Health Clinic F02.54-Outpatient Facility/Mobile Clinic F02.55-Outpatient Facility/Non-mobile Street Outreach F02.56-Outpatient Facility/PACTG Site			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		F02.57-Outpatient Facility/Primary Care Clinic, Not Specified F02.58-Outpatient Facility/School or University Clinic F02.OTH-Outpatient Facility/Other F02.UNK-Outpatient Facility/Unknown F03-Emergency Room F04-Screening, Diagnostic, Referral Agency (S,D,R) F04.01-(S,D,R) Blood Bank or Plasma Center F04.02-(S,D,R) Drug Treatment Center F04.03-(S,D,R) Family Planning Clinic F04.04-(S,D,R) HIV Case Management Agency F04.05-(S,D,R) HIV Counseling and Testing Site F04.07-(S,D,R) Insurance Screening F04.11-(S,D,R) STD Clinic F04.OTH-(S,D,R) Other F04.UNK-(S,D,R) Unknown F05-Laboratory F07-Other Specific Facility F07.01-Other Specific Facility/Correctional Facility F07.02-Other Specific Facility/Coroner or Medical Examiner			
facility_uid	A unique identifier for a healthcare facility.		YES	N/A	System
fax	The fax number of the facility.		NO	N/A	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
funding_cd	A code that indicates the type of HRSA funding a facility receives.	FUNDING_CD	YES	N/A	Optional
funding_flag	Does the facility receive HRSA funding?	YES_NO	YES	N/A	Optional
name1	Primary name of the facility.		YES	N/A	Optional
name2	Secondary or alternative name of the facility.		YES	N/A	Optional
phone	Phone number of the facility.		NO	N/A	Optional
setting_cd	A code identifying the setting of the facility, such as Federal, VA.	1-Public, unspecified 2-Federal, VA 3-Federal, IHS 4-Federal, military 5-Federal, corrections 6-Federal, other/unspecified 7-State 8-County/Parish 9-City/Town/Township 10-Private 999-Unknown	YES	N/A	Optional
ship_flag	A field used by the application to determine if the information for this facility needs to be transferred to CDC.	0 = Do not ship, 1 = Ship to CDC	NO	N/A	Optional
state_cd	State postal code of the facility's address.	STATE_CODES	YES	N/A	Optional
street_address1	Facility's primary street address.		NO	N/A	Optional
street_address2	Facility's secondary street address.		NO	N/A	Optional
zip_cd	Zip code for the facility's address.	ZIP_CITY (table)	YES	N/A	Optional
<b>FACILITY_EVENT</b>	<b>A table that maintains information pertaining to a person's events that involve a facility, such as facility at birth or facility at HIV diagnosis.</b>				
doc_belongs_to	Indicates if the facility event data (such as facility at HIV dx or facility at birth) belong to PERSON or CHILDn.	PERSON, MOTHER, CHILD	YES	All except DEATH_DOC and LAB_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
document_uid	A unique identifier for a document.		YES	All except DEATH_DOC and LAB_DOC	System
event_cd	A code that indicates the type of event that occurred.	01 - Facility of HIV diagnosis 02 - Facility of AIDS diagnosis 03 - Facility of perinatal exposure 05 - Hospital of birth 07 - Facility where child was transferred within 24 hours of delivery	YES	All except DEATH_DOC and LAB_DOC	Optional
facility_uid	The unique identifier of the facility associated with this event.	FACILITY_CODE (table)	YES	All except DEATH_DOC and LAB_DOC	Optional - System
provider_uid	The unique identifier of the provider associated with this event.	PROVIDER_CODE (table)	NO	All except DEATH_DOC and LAB_DOC	Optional - System
<b>ID</b>	<b>A table that maintains information on a person's identifiers.</b>				
doc_belongs_to	Indicates who the identifier belongs to: PERSON, MOTHER, or CHILD <i>n</i> .	PERSON, MOTHER, CHILD <i>n</i>	YES	ACRF, LEGACY_ADULT, PCRF, LEGACY_PEDIATRIC, BC	System
document_uid	A unique identifier for a document.		YES	All	System
id_cd	Code that indicates the type of identifier assigned to a person.	ID_CODE	YES	All	Refer to ID_CODE table for requirements for each variable
id_seq	Sequence identifier for a person's identification codes. A person can have multiple identification code types (id_cd_type) on the Person View document only.	1-99999999	YES	All	System



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
id_value	The value of the person's identifier.		YES	All	Refer to ID_CODE table for valid data element values for each variable
<b>ID_CODE</b>	<b>A table that contains all distinct ID.id_cd values and associated descriptions, including any locally-defined ID types.</b> <b>*Required for the stateno associated with the state of report and the cityno associated with the applicable city of report.</b>				
001	FL STATENO		YES	All	Optional*
003	HRSA URN		NO	All	Optional
004	Medicaid Number		NO	All	Optional
005	GA STATENO		YES	All	Optional*
006	PA STATENO		YES	All	Optional*
007	Ryan White Number		NO	All	Optional
008	AIDS Drug Assistance Program (ADAP) Number		NO	All	Optional
009	STD*MIS Number		YES	All	Optional
010	Prison Number		NO	All	Optional
011	RVCT (TB) Number		YES	All	Optional
012	Social Security Number (SSN)		NO	All	Optional
013	Social Security Number Alias		NO	All	Optional
015	CA Non-named Code (reported)		NO	All	Optional
016	CA Non-named Code (verified)		NO	All	Optional
017	CT Coded Identifier (reported)		NO	All	Optional
019	DC Unique Id (reported)		NO	All	Optional
020	DC Unique Id (verified)		NO	All	Optional
021	DE Coded Identifier (reported)		NO	All	Optional
022	DE Coded Identifier (verified)		NO	All	Optional
023	HI Unnamed Test Code (reported)		NO	All	Optional
024	HI Unnamed Test code (verified)		NO	All	Optional
025	IL Patient Code Number (reported)		NO	All	Optional
026	IL Patient Code Number (verified)		NO	All	Optional
027	Philadelphia, PA Unique Code (reported)		NO	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
028	Philadelphia, PA Unique Code (verified)		NO	All	Optional
029	MA Coded Identifier (reported)		NO	All	Optional
030	MA Coded Identifier (verified)		NO	All	Optional
031	MD Unique Identifier (reported)		NO	All	Optional
032	MD Unique Identifier (verified)		NO	All	Optional
033	ME Coded Identifier (reported)		NO	All	Optional
034	ME Coded Identifier (verified)		NO	All	Optional
035	MT Coded Identifier (reported)		NO	All	Optional
036	MT Coded Identifier (verified)		NO	All	Optional
037	OR Coded Identifier (reported)		NO	All	Optional
038	OR Coded Identifier (verified)		NO	All	Optional
041	RI Coded Identifier (reported)		NO	All	Optional
042	RI Coded Identifier (verified)		NO	All	Optional
043	VT Non-named Code (reported)		NO	All	Optional
044	VT Non-named Code (verified)		NO	All	Optional
045	WA Non-named Coded Id (reported)		NO	All	Optional
046	WA Non-named Coded Id (verified)		NO	All	Optional
047	PATNO (HARS)		YES	All	Optional
048	HIVNO (HARS)		YES	All	Optional
049	Medical Record Number (MEDRECNO)		NO	All	Optional
050	TX STATENO		YES	All	Optional*
051	Houston, TX CITYNO		YES	All	Optional*
052	LA STATENO		YES	All	Optional*
053	WA STATENO		YES	All	Optional*
054	MI STATENO		YES	All	Optional*
055	AL STATENO		YES	All	Optional*
056	NJ STATENO		YES	All	Optional*
059	Counseling and Testing		NO	All	Optional
067	WA Non-named Code (generated)		NO	All	Optional
069	DC Unique Id (generated)		NO	All	Optional
070	DE Coded Identifier (generated)		NO	All	Optional
071	HI Unnamed Test Code (generated)		NO	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
072	IL Patient Code Number (generated)		NO	All	Optional
073	Philadelphia, PA Unique Code (generated)		NO	All	Optional
074	MA Coded Identifier (generated)		NO	All	Optional
075	MD Unique Identifier (generated)		NO	All	Optional
076	ME Coded Identifier (generated)		NO	All	Optional
077	MT Coded Identifier (generated)		NO	All	Optional
078	OR Coded Identifier (generated)		NO	All	Optional
079	PR Coded Identifier (retired)		NO	All	Optional
080	VT Non-named Code (generated)		NO	All	Optional
081	CA Non-named Code (generated)		NO	All	Optional
082	CT Coded Identifier (generated)		NO	All	Optional
083	RI Coded Identifier (generated)		NO	All	Optional
084	WA Non-named Code Alias (reported)		NO	All	Optional
086	CA Non-named Code Alias (reported)		NO	All	Optional
090	DC Unique Id Alias (reported)		NO	All	Optional
092	DE Coded Identifier Alias (reported)		NO	All	Optional
094	HI Unnamed Test Code Alias (reported)		NO	All	Optional
096	IL Patient Code Number Alias (reported)		NO	All	Optional
098	Philadelphia, PA Unique Code Alias (reported)		NO	All	Optional
100	MA Coded Identifier Alias (reported)		NO	All	Optional
102	MD Unique Identifier Alias (reported)		NO	All	Optional
104	ME Coded Identifier Alias (reported)		NO	All	Optional
106	MT Coded Identifier Alias (reported)		NO	All	Optional
108	OR Coded Identifier Alias (reported)		NO	All	Optional
112	RI Coded Identifier Alias (reported)		NO	All	Optional
114	VT Non-named Code Alias (reported)		NO	All	Optional
132	UCSF Patient Identifier		NO	All	Optional
133	Reporting Health Department Number (generic cityno)		YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
134	AK STATENO		YES	All	Optional*
135	AZ STATENO		YES	All	Optional*
136	AR STATENO		YES	All	Optional*
137	CA STATENO		YES	All	Optional*
138	CO STATENO		YES	All	Optional*
139	CT STATENO		YES	All	Optional*
140	DE STATENO		YES	All	Optional*
141	HI STATENO		YES	All	Optional*
142	ID STATENO		YES	All	Optional*
143	IL STATENO		YES	All	Optional*
144	IN STATENO		YES	All	Optional*
145	IA STATENO		YES	All	Optional*
146	KS STATENO		YES	All	Optional*
147	KY STATENO		YES	All	Optional*
148	ME STATENO		YES	All	Optional*
149	MD STATENO		YES	All	Optional*
150	MA STATENO		YES	All	Optional*
151	MN STATENO		YES	All	Optional*
152	MS STATENO		YES	All	Optional*
153	MO STATENO		YES	All	Optional*
154	MT STATENO		YES	All	Optional*
155	NE STATENO		YES	All	Optional*
156	UT STATENO		YES	All	Optional*
157	VT STATENO		YES	All	Optional*
158	VA STATENO		YES	All	Optional*
159	WV STATENO		YES	All	Optional*
160	WI STATENO		YES	All	Optional*
161	WY STATENO		YES	All	Optional*
162	NV STATENO		YES	All	Optional*
163	NH STATENO		YES	All	Optional*
164	NM STATENO		YES	All	Optional*
165	NY STATENO		YES	All	Optional*

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
166	NC STATENO		YES	All	Optional*
167	ND STATENO		YES	All	Optional*
168	OH STATENO		YES	All	Optional*
169	OK STATENO		YES	All	Optional*
170	OR STATENO		YES	All	Optional*
171	RI STATENO		YES	All	Optional*
172	SC STATENO		YES	All	Optional*
173	SD STATENO		YES	All	Optional*
174	TN STATENO		YES	All	Optional*
175	New York, NY CITYNO		YES	All	Optional*
176	American Samoa STATENO		YES	All	Optional*
177	Mariana Islands STATENO		YES	All	Optional*
178	DC STATENO		YES	All	Optional*
179	Guam STATENO		YES	All	Optional*
180	Puerto Rico STATENO		YES	All	Optional*
181	Virgin Islands STATENO		YES	All	Optional*
182	San Francisco, CA CITYNO		YES	All	Optional*
183	Los Angeles, CA CITYNO		YES	All	Optional*
184	Chicago, IL CITYNO		YES	All	Optional*
185	Philadelphia, PA CITYNO		YES	All	Optional*
186	PATNO (ASD)		YES	All	Optional
187	INS Number		NO	All	Optional
188	KY Unique Code Alias (Retired)		NO	All	Optional
189	Tracking ID		NO	All	Optional
190	Generic ID		NO	All	Optional
191	PEMS Client Unique Key		NO	All	Optional
192	PEMS Local Client Key		NO	All	Optional
193	PEMS Form ID		NO	All	Optional
195	Palau STATENO		YES	All	Optional
196	Marshall Islands STATENO		YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
197	MMP PARID		YES	All	Optional
198	FIMR ID		YES	All	Optional
199	Federated States of Micronesia STATENO		YES	All	Optional*
200	EvalWeb Client ID		NO	All	Optional
201	EvalWeb Form ID		YES	All	Optional
202	EvalWeb Partner Services Case Number		YES	All	Optional
203	Integrated Disease Surveillance System Person ID		No	All	Optional
204	Integrated Disease Surveillance System Event ID		No	All	Optional
<b>INVESTIGATION_CASE</b>	<b>A table that maintains the details of the HIV case investigation.</b>				
document_uid	A unique identifier for a document.		YES	ACRF	System
invest_case_seq	Sequence number to make the record unique.		YES	ACRF	System
invest_type_cd	Type of investigation	0 - Transmission Cluster 1 - Not in care	YES	ACRF	Required
invest_ident_method	How person was first identified as needing investigation.	01 - Health department HIV surveillance system (e.g., eHARS) 02 - Health department integrated data system 03 - Provider report 04 - Transmission cluster investigation 05 - Elevated viral load investigation 06 - Partner services investigation 07 - Medical Monitoring Project (MMP) 88 - Other	YES	ACRF	Required
invest_ident_dt	Date first identified as needing investigation	YYYYMMDD	YES	ACRF	Required
invest_incl	Included in investigation.	Y - Included in investigation N - Excluded from investigation	YES	ACRF	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
invest_start_dt	Date investigation opened.	YYYYMMDD	YES	ACRF	Required
invest_dispo	Investigation disposition.	1 - Deceased 2 - Resides out of jurisdiction 3 - In care 4 - Not in care 5 - Unable to determine	YES	ACRF	Required
invest_dispo_dt	Investigation disposition date.	YYYYMMDD	YES	ACRF	Required
invest_dispo_method	Basis of investigation disposition.	1 - Database/record search, only 2 - Patient contact/field investigation, only 3 - Database/record search and patient contact/field investigation	YES	ACRF	Required
int_dispo_dt	Intervention disposition date.	YYYYMMDD	YES	ACRF	Required
int_dispo	Intervention disposition.	1 —No linkage/re- engagement intervention initiated 2 - Linkage/re-engagement intervention declined by client 3 - Returned to care before linkage/re-engagement intervention was initiated 4 - Linkage/re-engagement intervention initiated, not successfully linked to/re- engaged in care 5 - Linked to/re-engaged in care, documented 6 - Linked to/re-engaged in care, client self-report, only 7 - Linkage/re-engagement status unknown	YES	ACRF	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>INVESTIGATION_CLUSTER</b>	<b>A table that maintains the details of molecular cluster investigation.</b>				
cluster_uid	Unique cluster ID number.	A-Z, 0-9, -, _, blank	YES	ACRF	Required
cluster_ident_method	Method of cluster identification.	01 - State/local molecular cluster analysis 02 - National molecular cluster analysis 03 - State/local time-space cluster analysis 04 - National time-space cluster analysis 05 - Provider notification 06 - Partner services notification 88 - Other	YES	ACRF	Required
document_uid	A unique identifier for a document.		YES	ACRF	System
invest_cluster_seq	Sequence number to make the record unique.		YES	ACRF	System
person_ident_met	How person was identified as part of this cluster.	1 - Through analysis/notification 2 - Through investigation	YES	ACRF	Required
person_ident_dt	Date person was identified as part of this cluster.	YYYYMMDD	YES	ACRF	Required
<b>LAB</b>	<b>A table that maintains information on a person's diagnostic tests and STARHS results.</b>				
accession_number	An identifier assigned by the lab to a specimen when received; acts as a tracking mechanism for the specimen.		NO	ACRF, PCRF, LAB_DOC	Optional
case_cd	For application use, a code associating a diagnostic test with the HIV/AIDS case definition algorithm.	LAB_TEST_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	System
clia_uid	The CLIA provider number of the laboratory that performed the test.	CLIA_CODE (table)	YES	ACRF, PCRF, LAB_DOC	Optional
comments	Notes or comments regarding a lab test entered by a user. These values are transferred to CDC.		YES	ACRF, PCRF, LAB_DOC	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
document_uid	A unique identifier for a document.		YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	System
facility_uid	The unique identifier of the facility that ordered the test.	FACILITY_CODE (table)	YES	ACRF, PCRF, LAB_DOC	Optional - System
lab_seq	Sequence identifier for a person's laboratory results.		YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	System
lab_test_cd	The eHARS defined codes to identify lab tests	LAB_TEST_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required
lab_test_type	The type of lab test.	LAB_TEST_TYPE <b>(As of version 4.0 the values below have been retired from usage.)</b> TYPE_OF_KIT TYPE_OF_KIT_STARHS TYPE_OF_KIT_VL	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional if the test is rapid
manufacturer	The manufacturer of the test (applicable to viral load tests only)	01-Bayer Diagnostics 02-Organon Teknika 03-Roche Molecular Systems Inc. 04-Abbott Laboratories 05-ABBOTT Molecular Inc. 06-Alere 07-Avioq Inc. 08-BioLife Plasma Services 09-bioLytical Laboratories Inc. 10-Bio-Rad Laboratories 11-Celera Diagnostics	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		12-Chembio Diagnostic Systems Inc. 13-Gen-Probe Inc. 14-Home Access Health Corp. 15-Maxim Biomedical Inc. 16-MedMira Laboratories Inc. 17-National Genetics Institute 18-OraSure Technologies 19-Ortho-Clinical Diagnostics Inc. 21-Sanochemia Pharmazeutika AG 22-Siemens Healthcare Diagnostics Inc. 23-Trinity Biotech 24-Becton Dickinson 25-Beckman Coulter 26-Cytognos 27-Guava Technologies 28-Partec 29-Invitrogen/Dynal biotech 30-PointCare technologies 31-Sysmex 32-i+MED Laboratories Co. Ltd. 33-Visible Genetics 34-Applied Biosystems 35-Virco 36-bioMerieux, Inc 37-Siemens Medical Solutions Diagnostics 38-Chiron Corporation 40-Streck 41-DiaSorin			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		42-Hologic 88-Other 99-Unknown			
provider_uid	The unique identifier of the provider who ordered the test.	PROVIDER_CODE (table)	NO	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional-System
receive_dt	The date the lab that performed the test received the specimen from either a healthcare provider or another laboratory.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result	The result value including the optical density for STARHS.	LAB_RESULT_VALUE (but depends upon the test)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required when entering a lab test
result_interpretation	An interpretation of the lab result. For viral load tests, values include: within range =, below range (limit) <, above range (limit) >. For STARHS tests the STARHS_RESULT values as found in LOOKUP_CODE table.	RESULT_INTERPRETATION - For viral load tests STARHS_RESULT - For STARHS tests Old HARS value "I" (indeterminate) [viewable only]	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result_range_lower	The lower boundary reference range or detection limit for viral load.	0-999.999,999	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result_range_upper	The upper boundary reference range or detection limit for viral load.	0-999.999,999	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
result_rpt_dt	The date the test result was reported or processed at the lab.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
result_units	The reported units.	RESULT_UNITS_CD4, RESULT_UNITS	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required when entering a CD4 test
sample_dt	The date the specimen was collected.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC	Required when entering a lab test
sample_id	A unique identifier used to distinguish samples; may be specimen number or ID.		NO	ACRF, PCRF, LAB_DOC	Optional
specimen	The type of specimen collected.	BLD - Blood OTH - Other SAL - Saliva UNK - Unknown URN - Urine	YES	ACRF, PCRF, LAB_DOC	Optional
sreason	The reason the STARHS specimen was not sent for testing.	1 - Quantity not sufficient 2 - Specimen never received at public lab 3 - Specimen broke in transit 4 - Other 5 - Not sufficient antibodies	YES	ACRF, PCRF, LAB_DOC	Optional
starhs_sample_id	If this is a confirmatory test aliquoted for STARHS, the STARHS specimen ID.		YES	ACRF, PCRF, LAB_DOC	If lab_test_cd=EC-023, EC-024, EC-025, EC-026, or EC-027 then this variable is REQUIRED
<b>LAB_ANALYTE</b>	<b>A table that contains the HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay lab test's analyte results.</b>				
document_uid	A unique identifier for a document.		YES	ACRF, PCRF, LAB_DOC	System
lab_seq	Sequence identifier for a person's laboratory results.		YES	ACRF, PCRF, LAB_DOC	System
lab_test_cd	The eHARS defined codes to identify lab tests	LAB_TEST_CODE (table)	YES	ACRF, PCRF, LAB_DOC	Required
result_interpretation	An interpretation of the lab result.	RESULT_INT_ANALYTE	YES	ACRF, PCRF, LAB_DOC	Required when entering a lab test
result	The result value.	0.00000-9999.99999, <, >, =	YES	ACRF, PCRF, LAB_DOC	Optional
result_units	The reported units	IDX	YES	ACRF, PCRF, LAB_DOC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
<b>LAB_GENOTYPE</b>	<b>A table that contains the gene sequence from a person's genotype diagnostic test.</b>				
document_uid	A unique identifier for a document.		YES	ACRF, PCRF, LAB_DOC	System
genotype_sequence	The genotype sequence result from a genotype diagnostic test.	GENE_VALIDATION	YES	ACRF, PCRF, LAB_DOC	Required
lab_seq	Sequence identifier for a person's laboratory results.		YES	ACRF, PCRF, LAB_DOC	System
<b>OBSERVATION</b>	<b>A table that maintains information on a person's observations.</b>				
document_uid	An internal unique identifier for a document. For person-based local fields, the ehars_uid is stored in this field. For document-based local fields, the document_uid is stored in this field.		YES	All	System
obs_uid	An internal unique identifier for an observation.	OBSERVATION_CODE (table)	YES	All	Refer to OBSERVATION_CODE table for requirements for each variable
obs_value	The value for the observed object.		YES	All	Refer to OBSERVATION_CODE table for valid data element values for each variable
<b>OBSERVATION_CODE</b>	<b>A table that contains all distinct obs_value and associated descriptions.</b>				
1	Report status		YES	All	Optional
2	HARS Legacy - Laboratory name		YES	All	Legacy HARS
3	HARS Legacy - Other facility type at HIV diagnosis (specify)		YES	All	Legacy HARS
4	HARS Legacy - Has patient received a physical exam for this condition?	YES_NO_UNK	YES	All	Legacy HARS
5	HARS Legacy - Other facility type at perinatal exposure (specify)		YES	All	Legacy HARS
6	If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?	YES_NO_UNK	YES	All	Required if laboratory test not documented

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
7	Date patient was confirmed by a physician as HIV infected	YYYYMMDD	YES	All	Required if laboratory test not documented and physician diagnosis
8	Entered age at HIV diagnosis (years)		YES	All	Optional
9	Entered age at AIDS diagnosis (years)		YES	All	Optional
10	Clinical record reviewed	YES_NO	YES	All	Optional
11	Date patient was diagnosed as asymptomatic	YYYYMMDD	YES	All	Optional
12	Date patient was diagnosed as symptomatic	YYYYMMDD	YES	All	Optional
13	HARS Legacy - Other facility type at AIDS diagnosis (specify)		YES	All	Legacy HARS
14	Has patient been informed of his/her HIV infection?	YES_NO_UNK	YES	All	Optional
15	By whom patient's partners will be notified and counseled about their HIV exposure	PATIENT_NOTIFIER	YES	All	Optional
16	Is patient receiving or has patient been referred for medical services?	YES_NO_UNK	YES	All	Optional
17	Is patient receiving or has patient been referred for substance abuse treatment services?	YES_NO_NA_UNK	YES	All	Optional
18	HARS Legacy - Follow up date		YES	All	Legacy HARS
19	HARS Legacy - Follow up status of patient	1=Active follow-up 2=Moved from state 3=Provider out of state 4=Lost to follow-up 9=Unknown	YES	All	Legacy HARS
20	HARS Legacy - Laboratory ID number		YES	All	Legacy HARS
21	HARS Legacy - Did patient have heterosexual relations with a person born outside of the U.S.?	YES_NO_UNK	YES	All	Legacy HARS
22	HARS Legacy - Country of person with whom patient had heterosexual relations	See HARS country codes	YES	All	Legacy HARS
23	Patient is receiving or has been referred for OB-GYN services	YES_NO_UNK	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
24	Is patient currently pregnant?	YES_NO_UNK	YES	All	Required
25	Has patient delivered live-born infant?	YES_NO_UNK	YES	All	Optional
26	HARS Legacy - Has child's mother had sex with a man born outside of the U.S.?	YES_NO_UNK	YES	All	Legacy HARS
27	HARS Legacy - Is patient receiving HIV prophylactic therapy?	YES_NO_UNK	YES	All	Legacy HARS
28	HARS Legacy - Has patient been referred for treatment?	YES_NO_UNK	YES	All	Legacy HARS
29	HARS Legacy - Country of man with whom child's mother had sex	See HARS country codes	YES	All	Legacy HARS
31	HARS Legacy - Method of partner notification	1=Patient referred 2=Health department referred 8=Other provider	YES	All	Legacy HARS
32	HARS Legacy - Source of AIDS report	LEGACY_SOURCE	YES	All	Legacy HARS
33	HARS Legacy - Source of HIV report	LEGACY_SOURCE	YES	All	Legacy HARS
34	HARS Legacy - Source of AIDS report (specify)		YES	All	Legacy HARS
35	HARS Legacy - Source of HIV report (specify)		YES	All	Legacy HARS
39	Date of last medical evaluation	YYYYMMDD	YES	All	Optional
40	Date of initial evaluation for HIV infection	YYYYMMDD	YES	All	Optional
41	Was reason for initial HIV evaluation due to clinical signs/symptoms?	YES_NO_UNK	YES	All	Optional
42	Date of mother's first HIV positive test	YES_NO_UNK	YES	All	Optional
43	eHARS Retired — Was mother counseled about HIV testing during this pregnancy, labor, or delivery?	YES_NO_UNK	YES	All	Optional
44	eHARS Retired — If HIV tests were not positive or were not done, does this patient have an immunodeficiency that would disqualify him/her from AIDS case definition?	YES_NO_UNK	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
45	Is patient confirmed by a physician as not HIV infected?	YES_NO_UNK	YES	All	Optional
46	Date patient confirmed by physician as not HIV infected	YYYYMMDD	YES	All	Optional
47	Is child's birth history available?	YES_NO_UNK	YES	All	Optional
48	Entered diagnostic status at report	1 - Adult HIV 2 - Adult AIDS 3 - Perinatal HIV exposure 4 - Pediatric HIV 5 - Pediatric AIDS 6 - Pediatric seroreverter 9 - Unknown	YES	All	Optional
58	HARS Legacy - Mother's type of coagulation disorder	1=Hemophilia A 2=Hemophilia B 8=Other disorder	YES	All	Legacy HARS
74	HARS Legacy - Was mother diagnosed with HIV/AIDS?	YES_NO_UNK	YES	All	Legacy HARS
75	HARS Legacy - Was mother diagnosed with HIV/AIDS prior to child's birth?	YES_NO_UNK	YES	All	Legacy HARS
76	Has child received neonatal zidovudine?	YES_NO_UNK	YES	All	Retired
78	Has child received other neonatal anti-retroviral therapy?	YES_NO_UNK	YES	All	Retired
81	Has patient received anti-retroviral therapy?	YES_NO_UNK	YES	All	Retired
83	Has patient received PCP prophylaxis?	YES_NO_UNK	YES	All	Optional
84	Date PCP prophylaxis started	YYYYMMDD	YES	All	Optional
86	Is patient enrolled in government/other clinical trial?	PATIENT_ENROLLED_TRIAL	YES	All	Optional
87	Is patient enrolled at clinic?	PATIENT_ENROLLED_CLINIC	YES	All	Optional
88	HARS Legacy - Primary source of reimbursement for medical treatment	1=Medicaid 2=Private coverage 3=No coverage 4=Other public fund 7=Government program 9=Unknown	YES	All	Legacy HARS
89	Child's primary caretaker	1 - Biological parent(s) 2 - Other relative	YES	All	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		3 - Foster/Adoptive parent, relative 4 - Foster/Adoptive parent, unrelated 7 - Social service agency 8 - Other (please specify in comments) 9 - Unknown			
90	HARS Legacy - For pediatric presumptive AIDS before 10/94, was lymphocyte count low (< 1000 ul)?	YES_NO_UNK	YES	All	Legacy HARS
91	HARS Legacy - For pediatric presumptive AIDS before 10/94, was CD4/CD8 ratio low (< 1000 ul)?	YES_NO_UNK	YES	All	Legacy HARS
92	HARS Legacy - For pediatric presumptive AIDS before 10/94, total serum immunoglobulins category	1=<1500 mg/dl 2=1500-2500 3=>2500 mg/dl 9=Unknown	YES	All	Legacy HARS
93	HARS Legacy - For pediatric presumptive AIDS before 10/94, highest total serum immunoglobulins value (mg/dl)		YES	All	Legacy HARS
94	HARS Legacy - For pediatric presumptive AIDS before 10/94, date of highest total serum immunoglobulins		YES	All	Legacy HARS
95	HARS Legacy - Was mother known to be uninfected after child's birth?	YES_NO_UNK	YES	All	Legacy HARS
96	HARS Legacy - Scheduled follow-up: TB update	range: 0-9, A-Z	YES	All	Legacy HARS
99	HARS Legacy - Scheduled follow-up: heterosexual case update	range: 0-9, A-Z	YES	All	Legacy HARS
100	HARS Legacy - Father's birthplace	1=US 7=US possession 8=Other 9=Unknown	YES	All	Legacy HARS

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
101	HARS Legacy - Father's country of birth	See HARS country codes	YES	All	Legacy HARS
102	HARS Legacy - Father's U.S. dependency of birth	See HARS US dependency codes	YES	All	Legacy HARS
114	Entered age at HIV diagnosis (months)		YES	All	Optional
115	Entered age at AIDS diagnosis (months)		YES	All	Optional
116	HARS Legacy - Clinical status assessed within one month of initial report	1=Asymptomatic 2=Symptomatic for HIV/AIDS	YES	All	Legacy HARS
118	HARS Legacy - NDI match category	1=Death not previously known 2=Death previously known; certificate identified by NDI 3=Death and certificate previously identified	YES	All	Legacy HARS
128	HARS Legacy - Scheduled follow-up: immunologic case update	range: 0-9, A-Z	YES	All	Legacy HARS
138	HARS Legacy - Physician name		YES	All	Legacy HARS
139	HARS Legacy - Patient name		YES	All	Legacy HARS
179	HARS Legacy - Comments from ARS		YES	All	Legacy HARS
180	HARS Legacy - Was this child referred?	1=Yes, by health dept. 2=Yes, by health care/provider 3=No, family refused 4=No 9=Unknown	YES	All	Legacy HARS
181	HARS Legacy - Comment line 1		YES	All	Legacy HARS
182	HARS Legacy - Comment line 2		YES	All	Legacy HARS
183	HARS Legacy - Comment line 3		YES	All	Legacy HARS
184	HARS Legacy - Comment line 4		YES	All	Legacy HARS
186	HARS Legacy - Date initial AIDS form completed	YYYYMMDD	YES	All	Legacy HARS
187	HARS Legacy - State GSA geographic code of current residence	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
189	HARS Legacy - Form (Adult of Pediatric)	A=Adult P=Pediatric	YES	All	Legacy HARS

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
190	HARS Legacy - Date initial HIV form completed	YYYYMMDD	YES	All	Legacy HARS
192	HARS Legacy - Date of HIV diagnosis reported at facility	YYYYMMDD	YES	All	Legacy HARS
194	HARS Legacy - Date of AIDS diagnosis reported at facility	YYYYMMDD	YES	All	Legacy HARS
196	HARS Legacy - State GSA geographic code of residence at HIV diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
197	HARS Legacy - State GSA geographic code of facility at HIV diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
198	HARS Legacy - Has child received IVIG therapy?	YES_NO_UNK	YES	All	Legacy HARS
199	HARS Legacy - Mother received blood products	YES_NO_UNK	YES	All	Legacy HARS
200	HARS Legacy - Date of perinatal HIV exposure reported at facility	YYYYMMDD	YES	All	Legacy HARS
202	HARS Legacy - State GSA geographic code of facility at perinatal HIV exposure	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
204	HARS Legacy - State GSA geographic code of residence at AIDS diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
205	HARS Legacy - Record shipment to CDC indicator	N=No Y, 2, ....=Yes	YES	All	Legacy HARS
206	HARS Legacy - State GSA geographic code of facility at AIDS diagnosis	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
207	HARS Legacy - State GSA geographic code of reporting state	(FIPS_CITY.state_fips)	YES	All	Legacy HARS
208	HARS Legacy - Record status	A - Active record B - Deleted record E - Fields in error F - Deleted with fields in error R – Required fields missing S – Deleted with reqd fields	YES	All	Legacy HARS

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		missing V - Pending verification W - Deleted before verified X – Reuse record in Database Z – ID number change			
210	HARS Legacy - Physician phone		YES	All	Legacy HARS
211	HARS Legacy - Reporting state	(FIPS_CITY.state_cd)	YES	All	Legacy HARS
212	HARS Legacy - Mother receive any other anti-retroviral medication during pregnancy (specify)		YES	All	Legacy HARS
220	Primary source of reimbursement for medical treatment at time of AIDS diagnosis	01 - CHAMPUS/TRICARE 02 - CHIP 03 - Medicaid 04 - Medicaid, pending 05 - Medicare 06 - Other public funding 07 - Private insurance, HMO 08 - Private insurance, PPO 09 - Private insurance, unspecified 10 - Self insured 11 - State funded, COBRA 12 - State funded, other 13 - State funded, unspecified 14 - VA 15 - No health insurance 88 - Other 99 - Unknown	YES	All	Optional
221	Primary source of reimbursement for medical treatment at time of HIV diagnosis	01 - CHAMPUS/TRICARE 02 - CHIP 03 - Medicaid 04 - Medicaid, pending 05 - Medicare 06 - Other public funding	YES	All	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		07 - Private insurance, HMO 08 - Private insurance, PPO 09 - Private insurance, unspecified 10 - Self insured 11 - State funded, COBRA 12 - State funded, other 13 - State funded, unspecified 14 - VA 15 - No health insurance 88 - Other 99 - Unknown			
222	Did the documented laboratory test results meet approved alternate HIV testing algorithm criteria?	YES_NO_UNK	YES	All	Required if laboratory tests meet approved alternative algorithm
223	If YES, provide specimen collection date of earliest positive test for this algorithm	YYYYMMDD	YES	All	Required if laboratory tests meet approved alternative algorithm
224	Ever taken any ARVs?	YES_NO_UNK	YES	ACRF, PCRF	Required
225	Main source of antiretroviral (ARV) use information	1 - Provider Report 2 - Patient Interview 3 - Medical Record Review 4 - NHM&E 5 - Other	YES	ACRF	Required
227	Date patient reported information	YYYYMMDD	YES	ACRF	Required
229	Date of last use of PCP prophylaxis	YYYYMMDD	YES	ACRF, PCRF	Optional
230	eHARS Retired -Did mother receive zidovudine(ZDV,AZT) prior to this pregnancy?	YES_NO_UNK	YES	PCRF	Retired
231	eHARS Retired - Did mother receive zidovudine(ZDV,AZT) during pregnancy	YES_NO_REF_UNK	YES	PCRF	Retired

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
232	eHARS Retired -If yes, what week of pregnancy was zidovudine (ZDV, AZT) start)	01-52	YES	PCRF	Retired
233	eHARS Retired -Did mother receive any other Antiretroviral medication during pregnancy?	YES_NO_UNK	YES	PCRF	Retired
234	eHARS Retired -Did mother receive zidovudine(ZDV,AZT) during labor/delivery?	YES_NO_REF_UNK	YES	PCRF	Retired
235	eHARS Retired -Did mother receive any other Antiretroviral medication during labor/delivery	YES_NO_UNK	YES	PCRF	Retired
236	Did mother receive any ARVs prior to this pregnancy?	YES_NO_UNK	YES	PCRF	Optional
237	Did mother receive any ARVs during pregnancy?	YES_NO_UNK	YES	PCRF	Optional
238	Did mother receive any ARVs during labor/delivery?	YES_NO_UNK	YES	PCRF	Optional
239	Evidence of receipt of HIV medical care other than laboratory test result	1 – Yes, documented 2 – Yes, client self-report, only	YES	ACRF	Optional
240	Date of medical visit or prescription	YYYYMMDD	YES	ACRF	Optional
241	Suspect acute HIV infection	YES_NO_UNK	YES	ACRF	Optional
242	Clinical sign/symptom consistent with acute retroviral syndrome	YES_NO_UNK	YES	ACRF	Optional
243	Date of acute retroviral syndrome sign/symptom onset	YYYYMMDD	YES	ACRF	Optional
244	Other evidence suggestive of acute HIV infection	YES_NO_UNK	YES	ACRF	Optional
245	Date of other evidence	YYYYMMDD	YES	ACRF	Optional
246	Description of other evidence	[A-Z,0-9, special character]	YES	ACRF	Optional
247	eHARS Retired - 1. If information on the mother is not available, was the child adopted, or in foster care?	YES_NO_NA	YES	PCRF	Retired
248	eHARS Retired -2. Records Abstracted		YES	PCRF	Retired
249	eHARS Retired -3. Weeks' gestation at first prenatal care visit.		YES	PCRF	Retired

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
250	eHARS Retired - 19. Was mothers HIV serostatus noted in prenatal care, labor and delivery and child's birth records?	YHIVP_YHIVN_NO_RNA_UN K	YES	PCRF	Retired
251	eHARS Retired -12. Were ARV's prescribed for the mother during this pregnancy: gestational age		YES	PCRF	Retired
252	eHARS Retired -14.Did mother receive ARV's during labor and delivery?: time received, type of administration		YES	PCRF	Retired
253	eHARS Retired -20.Were antiretroviral drugs prescribed for the child?: time started, art completed, stop codes		YES	PCRF	Retired
254	eHARS Retired -15. Was mother referred for HIV care after delivery?	YES_NO_ND_RNA_UNK	YES	PCRF	Retired
255	eHARS Retired -16a. Indicate first CD4 result after discharge from hospital (up to 6 months after discharge)		YES	PCRF	Retired
256	eHARS Retired -16b. Indicate first viral load after discharge from hospital (up to 6 months after discharge)		YES	PCRF	Retired
257	eHARS Retired -17. Birth information available	BNH_RNA	YES	PCRF	Retired
258	eHARS Retired -17. Onset of labor	YES_NO hh:mm:ssss MM/DD/YYYY	YES	PCRF	Retired
259	eHARS Retired -17. Admission to labor and delivery	YES_NO hh:mm:ssss MM/DD/YYYY	YES	PCRF	Retired
260	eHARS Retired - 7. Sibling date of birth, HIV serostatus, State No, City No		YES	PCRF	Retired
261	eHARS Retired - 8. Was substance use during pregnancy noted in medical or social work records?		YES	PCRF	Retired
262	eHARS Retired - 8b. If substances used, were any injected? Specify injected substance(s).		YES	PCRF	Retired

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
263	eHARS Retired - 9. Was a toxicology screen done on the mother (either during pregnancy or at the time of delivery)?		YES	PCRF	Retired
264	eHARS Retired - 10. Was a toxicology screen done on the infant at birth?	YPR_YNR_NO_TSND	YES	PCRF	Retired
265	eHARS Retired - Was this child breastfed?	YES_NO	YES	PCRF	Retired
266	eHARS Retired - Maternal stateno		YES	PCRF	Retired
<b>OI</b>	<b>A table that maintains information on a person's opportunistic infections (diseases indicative of AIDS).</b>				
document_uid	A unique identifier for a document.		YES	All	System
dx	A code indicating if the diagnosis was presumptive or definitive.	DEF_PRE	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
dx_dt	The date the AIDS defining condition was diagnosed.	YYYYMMDD	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional
oi_cd	A code indicating a person's AIDS defining conditions.	AD01 - Bacterial infection, multiple or recurrent (including Salmonella septicemia) AD02 - Candidiasis, bronchi, trachea, or lungs AD03 - Candidiasis, esophageal AD04 - Carcinoma, invasive cervical AD05 - Coccidioidomycosis, disseminated or extrapulmonary AD06 - Cryptococcosis, extrapulmonary AD07 - Cryptosporidiosis, chronic intestinal (>1 mo. duration) AD08 - Cytomegalovirus disease (other than in liver, spleen, or nodes)	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		AD09 - Cytomegalovirus retinitis (with loss of vision) AD10 - HIV encephalopathy AD11 - Herpes simplex: chronic ulcer(s) (>1 mo. duration) or bronchitis, pneumonitis, or esophagitis AD12 - Histoplasmosis, disseminated or extrapulmonary AD13 - Isosporiasis, chronic intestinal (> 1 mo. duration) AD14 - Kaposi's sarcoma AD15 - Lymphoid interstitial pneumonia and/or pulmonary lymphoid AD16 - Lymphoma, Burkitts (or equivalent term) AD17 - Lymphoma, immunoblastic (or equivalent term) AD18 - Lymphoma, primary in brain AD19 - Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary AD20 - M. tuberculosis, pulmonary AD21 - M. tuberculosis, disseminated or extrapulmonary AD22 - Mycobacterium, of other species or unidentified species,			

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		disseminated or extrapulmonary AD23 - Pneumocystis carinii pneumonia AD24 - Pneumonia, recurrent, in 12 mo. period AD25 - Progressive multifocal leukoencephalopathy AD26 - Salmonella septicemia, recurrent AD27 - Toxoplasmosis of brain, onset at >1 mo. of age AD28 - Wasting syndrome due to HIV			
oi_seq	Sequence identifier for a person's AIDS defining conditions.	0-99,999,999	YES	ACRF, PCRF, LEGACY_ADULT, LEGACY_PEDIATRIC	System
<b>OTHER_HEALTH_CONDI TIONS</b>	<b>A table that maintains the health conditions, other than HIV, of birthing person and infant during pregnancy, labor and delivery. This information is collected in the Birth History and Birthing Person History sections of Pediatric Case Report Forms (PCRF) documents.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System
condition_seq	Sequence number. Implement sequence number to way RISK and ADDRESS to handle all codes on PV.	0-999999	YES	PCRF, LEGACY_PEDIATRIC	System
condition_event_cd	Connects to the overall question or section to allow storage when data gathered for different questions for the same case.	CONDITION_EVENT_CD	YES	PCRF, LEGACY_PEDIATRIC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
condition_cd	Unique code for health condition	HEALTH_CONDITION_CD	YES	PCRF, LEGACY_PEDIATRIC	Optional
condition_value	Screening value or diagnosis value of other health condition.	YES_NO_UNK - only for new records, manual entry and ADI ND & RNA- valid for PHER converted data and will appear as greyed out options in manual entry drop-down box	YES	PCRF, LEGACY_PEDIATRIC	Optional
condition_dt	Date screening or performed or date condition diagnosed.	YYYYMMDD .	YES	PCRF, LEGACY_PEDIATRIC	Optional
doc_belongs_to	Indicates who the address data belong to: PERSON, MOTHER.	PERSON, MOTHER	YES	PCRF, LEGACY_PEDIATRIC PCRF, LEGACY_PEDIATRIC	System
<b>PERSON</b>	<b>A table that maintains demographic information about a person.</b>				
birth_country_cd	A code indicating the country of birth.	COUNTRY_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, LEGACY_CONSENT, LEGACY_TTH	Optional
birth_country_usd	A code indicating the specific U.S. dependency of birth.	COUNTRY_CODE (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, LEGACY_CONSENT, LEGACY_TTH	Optional
birth_sex	The person's biological sex at birth, as noted on the birth certificate.	F - Female M - Male	YES	All	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		U - Unknown			
current_gender	The person's current gender or psychosocial construct that most people use to classify a person as male, female, both, or neither. When eHARS is first installed and configured, the state determines whether or not this field is displayed.	F - Female FM - Transgender-Female to Male U - Unknown M - Male MF - Transgender-Male to Female AD - Additional Gender Identity	YES	All except BC	Required
current_sex	Physiological anatomy and biology that determines if someone is male, female, or intersexed. At installation, the state determines whether or not this field is displayed.	F - Female I - Intersexed M - Male	YES	All except BC	Retired
dob	The first known date of birth.	YYYYMMDD	YES	All	Required
dob_alias	The second known or alias date of birth.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, LEGACY_CONSENT, LEGACY_TTH	Optional
doc_belongs_to	Indicates if the demographics data belong to PERSON, MOTHER, FATHER, or CHILDn.	PERSON, MOTHER, FATHER, CHILDn	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC	System
document_uid	A unique identifier for a document.		YES	All	System
education	The level of education (optional field).	1 - 8th grade or less 2 - Some high school 3 - High school graduate, GED or equivalent 4 - Some college 5 - College degree 6 - Post-graduate work 7 - Some school, level unknown	NO	All except BC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
		9 - Unknown			
ethnicity1	Indicates if the person is of Hispanic or Latino origin. A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.	ETHNICITY	YES	All	Required
ethnicity2	Indicates if the person is of Hispanic or Latino origin. A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.	ETHNICITY	YES	All	Optional
gender_id_dt	The date the gender identity of the person was identified.	YYYYMMDD	YES	All except BC	Required
gender_other_specify	User entered gender identity when "other specify" is chosen.		YES	All except BC	Required
hars_race	For legacy HARS data, a read-only field indicating the person's race code entered in HARS previous to v6.0 (prior to implementation of Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity [ <a href="http://www.whitehouse.gov/omb/fedrereg/ombdir15.html">http://www.whitehouse.gov/omb/fedrereg/ombdir15.html</a> ]).	1-White, not Hispanic 2-Black, not Hispanic 3-Hispanic 4-Asian/Pacific Islander 5-American Indian/Alaska Native 9-Unknown	YES	LEGACY_ADULT, LEGACY_PEDIATRIC	Legacy HARS
hars_xrace	HARS expanded race.	HARS_XRACE	YES	LEGACY_ADULT, LEGACY_PEDIATRIC	Legacy HARS
hcw	Is this person a healthcare worker? (optional field)	YES_NO_UNK	YES	ACRF	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
hcw_occup	Occupation, if healthcare worker (optional field).	OCCUPATION	YES	ACRF, LEGACY_CONSENT, LEGACY_TTH	Optional
marital_status	The person's marital status.	A - Married and separated D - Divorced M - Married N - Not otherwise specified O - Other S - Single and never married U - Unknown W - Widowed	NO	All except PCRF	Optional
race1	Indicates the person's race.	RACE	YES	All	Required
race2	Indicates the person's race.	RACE	YES	All	Required
race3	Indicates the person's race.	RACE	YES	All	Required
race4	Indicates the person's race.	RACE	YES	All	Required
race5	Indicates the person's race.	RACE	YES	All	Required
sexual_orientation	The person's sexual orientation	SEXUAL_ORIENTATION	YES	All except BC	Required
sexual_orientation_id_dt	The date the sexual orientation of the person was identified.	YYYYMMDD	YES	All except BC	Required
sexual_orientation_other_spec	Use entered sexual orientation when "other specify" is chosen.		YES	All except BC	Required
vital_status	Indicates vital status at time form was completed—alive, dead, or unknown.	1 - Alive 2 - Dead 9 - Unknown	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC	Required
<b>PERSON_NAME</b>	<b>A table that maintains information on a person's names and Soundex codes.</b>				

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
doc_belongs_to	Indicates if the name belongs to PERSON, MOTHER, or CHILDn.	PERSON, MOTHER, CHILDn	YES	All	System
document_uid	A unique identifier for a document.		YES	All	System
first_name	The person's first name.		NO	All	Optional
first_name_sndx	The person's first name in a Soundex format.		NO	All	System
last_name	The person's last name. For hyphenated or last names containing two words, the standard is as follows: Smith Jones.		NO	All	Required
last_name_sndx	The person's last name in a Soundex format.		YES	All	System
middle_name	The person's middle name.		NO	All	Optional
name_prefix	The person's name prefix.		NO	All	Optional
name_suffix	The person's name suffix.		NO	All	Optional
name_use_cd	A code indicating the type of name being used, such as Maiden or Birth. The default value is Legal.	NAME_USE	YES	All	Optional
person_name_seq	Sequence identifiers for a person's name.	0-999,999,999	YES	All	System
removal_ind	A field used by the application to determine if the name removal utility has been applied to this row.	YES_NO	NO		System
<b>PREGNANCY_OUTCOME</b>	<b>A table to capture final outcome of previous pregnancies of birthing person.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
preg_outcome	Final outcome of pregnancy.	PREGNANCY_OUTCOME	YES	PCRF, LEGACY_PEDIATRIC	Optional
preg_seq	Auto-generated number to allow for multiple events per document.	0-9	YES	PCRF, LEGACY_PEDIATRIC	System
preg_outcome_dt	Year in which pregnancy event occurred.	YYYY.... YYYYMMDD 99999999	YES	PCRF, LEGACY_PEDIATRIC	Optional
<b>PRETEST_QUESTIONNAIRE</b>	<b>A table that maintains information on a person's pretest questionnaire.</b>				
document_uid	A unique identifier for the person's Pretest Questionnaire.		YES	ACRF, LEGACY_TTH	System
qhrtnw	Are you now taking any ARVs?	YES_NO	YES	ACRF, LEGACY_TTH	Optional
Ucts	Main source of testing history information.	UCTS	YES	ACRF, LEGACY_TTH	Required
ufposa	When you first tested positive for HIV, was the HIV test an anonymous test?	YES_NO_REF	YES	ACRF, LEGACY_TTH	Optional
ufposd	Date of first positive HIV test		YES	ACRF, LEGACY_TTH	Required
ufposd_self	First positive test result from self-test performed by patient	YES_NO_UNK	YES	ACRF	Required
ufps_site	Name of facility where first tested positive for HIV	SITE_CD	NO	ACRF, LEGACY_TTH	Optional
ufps_state	State where first tested positive for HIV	STATE_CODES_PR	YES	ACRF, LEGACY_TTH	Optional
ufpstyp	Type of facility where first tested positive for HIV	FACILITY_TYPE	YES	ACRF, LEGACY_TTH	Optional
uftstd	When was the first time you ever got tested for HIV?		YES	ACRF, LEGACY_TTH	Optional
ulstnd	Date of last negative HIV test		YES	ACRF, LEGACY_TTH	Required
ulstnd_sef	Last negative test result from a self-test performed by patient	YES_NO_UNK	YES	ACRF	Required
ulstngs	Type of facility where last tested negative for HIV	FACILITY_TYPE	YES	ACRF, LEGACY_TTH	Optional
ulstngs_site	Name of facility where last tested negative for HIV	SITE_CD	NO	ACRF, LEGACY_TTH	Optional



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
ulstngs_state	State where last tested negative for HIV	STATE_CODES_PR	YES	ACRF, LEGACY_TTH	Optional
ungtst	Ever had a negative HIV test?	YES_NO_REF_UNK	YES	ACRF, LEGACY_TTH	Required
unumtsts	Number of negative HIV tests within 24 months before first positive test	0-99	YES	ACRF, LEGACY_TTH	Required
unumtsts_self	Number of negative test results were self-tests performed by patient	0-99	YES	ACRF	Required
upastp	Ever had a positive HIV test result?	YES_NO_REF	YES	ACRF, LEGACY_TTH	Required
upnumtsts	For persons who had a previous positive test (Legacy Pre-test form only): In the two years before your first positive test, how many times did you get tested for HIV?	0-99	YES	ACRF, LEGACY_TTH	Legacy Incidence
uptests	Have you been tested for HIV before today?	YES_NO_REF	YES	ACRF, LEGACY_TTH	Optional
uqintd	Date patient reported information		YES	ACRF, LEGACY_TTH	Required
ur3_5sp	Reason for getting today's HIV test: If other reason, describe		YES	ACRF, LEGACY_TTH	Optional
ur4e_5sp	Reason for getting the first positive HIV test: If other reason, describe		YES	ACRF, LEGACY_TTH	Optional
ureas3_1	Reason for getting today's HIV test: Think you might have been exposed to HIV in the 6 months before the test	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_2	Reason for getting today's HIV test: Get tested on a regular basis and it is time to get tested again	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_3	Reason for getting today's HIV test: Just checking to make sure you are HIV negative	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_4	Reason for getting today's HIV test: Required by insurance, military, court, or other agency	YES_NO	YES	ACRF, LEGACY_TTH	Optional
ureas3_5	Reason for getting today's HIV test: Other reason you want to get tested	YES_NO	YES	ACRF, LEGACY_TTH	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
urs4e_1	Reason for getting the first positive HIV test: Thought you might have been exposed to HIV in the past 6 months before the test	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_2	Reason for getting the first positive HIV test: Got tested on a regular basis and it was time to get tested again	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_3	Reason for getting the first positive HIV test: Just checking to make sure you were HIV negative	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_4	HIV test required	YES_NO	YES	ACRF, LEGACY_TTH	Optional
urs4e_5	Reason for getting the first positive HIV test: Other reason you wanted to get tested	YES_NO	YES	ACRF, LEGACY_TTH	Optional
<b>PROVIDER_CODE</b>	<b>A table that maintains information on healthcare providers.</b>				
first_name	The first name of the healthcare provider.		NO	N/A	Optional
last_name	The last name of the healthcare provider.		NO	N/A	Optional
middle_name	The middle name of the healthcare provider.		NO	N/A	Optional
name_prefix	The name prefix of the healthcare provider.		NO	N/A	Optional
name_suffix	The name suffix of the healthcare provider.		NO	N/A	Optional
phone	The phone number of the healthcare provider.	7 or 10 digits	NO	N/A	Optional
provider_uid	A unique identifier for a healthcare provider.		NO	N/A	System
ship_flag	A field used by the application to determine if the information needs to be transferred to CDC		NO	N/A	System
specialty_cd	A code indicating the type of specialty for this health care provider.	SPECIALTY_CD	YES	N/A	Optional
<b>RIDR</b>	<b>A table that maintains information pertaining to a case's duplicate status review.</b>				

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
comments	Notes or comments pertaining to the duplicate status information entered for this person.		NO	ACRF, PCRF	Optional
document_uid	A unique identifier of the current document.		YES	ACRF, PCRF	System
duplicate_status	The status of the duplicate review, such as Pending or Same As.	1 - Same as 2 - Different than 3 - Pending	YES	ACRF, PCRF	Required if case identified as potential duplicate
ehars_uid	A unique identifier for the existing case.		YES	ACRF, PCRF	System
last_verify_dt	The date when the status of the duplicate review was last verified.	YYYYMMDD	YES	ACRF, PCRF	Optional
state_cd	The two character postal code of the state of the possible duplicate case.	STATE_CODES_PR	YES	ACRF, PCRF	Required if case identified as potential duplicate
stateno	The stateno identifier of the possible duplicate case.		YES	ACRF, PCRF	Required if case identified as potential duplicate
verify_by	The person who reviewed the duplicate status entry.		YES	ACRF, PCRF	Optional
<b>RISK</b>	<b>A table that maintains information on a person's risk factors.</b>				
cophi_status	Code that indicates the COPHI investigation status, if applicable.	1 - Open, under investigation 2 - Closed, confirmed COPHI 3 - Closed, investigated, not confirmed 4 - Closed, not a COPHI 5 - Will not be investigated, not confirmed 9 - Unknown	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Optional

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
detail	This field captures detailed information about risk factor—the type of clotting factor the person had or the occupation, if occupational exposure. <b>Note:</b> RISK.detail also stores NIR type information (1 = user entered [if date investigation was completed is entered], 2 = system assigned)	For R04, R30, R33, R32 => CLOTTING_FACTOR For R13 => OCCUPATION For R80, R81 => 1 = user entered [if date investigation was completed is entered], 2 = system assigned	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Optional
display	A field used by the application for display purposes.	A(adult), P(pediatric), H(hemophilia)	NO	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	System
document_uid	A unique identifier for a document.		YES	All	System
resolution_dt	The date the COPHI investigation was resolved.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Optional
risk_cd	Code indicating a risk factor (such as R03 indicating IDU).	RISK_CD (table)	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Refer to RISK_CD table for requirements for each variable
risk_seq	Sequence identifier for a person's modes of exposure.	0-99,999,999	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	System
risk_value	Code indicating the risk factor value (Y-Yes, N-No, U-Unknown, or 2-CDC confirmed) or the mother's infection status (1–9).	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Refer to RISK_CD table for valid data element values for each variable

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
trans_first_dt	If patient received transfusion of blood/blood components, the first date the patient received transfusion. <b>Note:</b> For user entered NIR (No Identified Risk), the date entered is stored in this field.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
trans_last_dt	If patient received transfusion of blood/blood components, the last date the patient received transfusion. <b>Note:</b> When the system identifies NIR, the system date is stored in this field.	YYYYMMDD	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
<b>RISK_CD</b>	<b>A table that contains all distinct RISK.risk_cd values and associated descriptions.</b>				
R01	Sex with male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R02	Sex with female	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R03	Injected non-prescription drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R04	Received clotting factor for hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R05	Heterosexual contact with person who injected drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC,	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
				LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	
R06	Heterosexual contact with bisexual male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R07	Heterosexual contact with person with hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R08	Heterosexual contact with transfusion recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R09	Heterosexual contact with transplant recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R10	Heterosexual contact with person with AIDS or documented HIV infection, risk not specified	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R11	Received transfusion of blood/blood components (other than clotting factor)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R12	Received transplant of tissue/organs or artificial insemination	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
R13	Worked in a health care or clinical laboratory setting	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R14	Sexual contact with male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R15	Sexual contact with female	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R16	Child's biological mother's infection status	For R16 only => M_INFECTION_STATUS	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R17	Perinatally acquired HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R18	Injected non-prescription drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R19	Heterosexual contact with person who injected drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
R20	Heterosexual contact with bisexual male	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R21	Heterosexual contact with male with hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R22	Heterosexual contact with transfusion recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R23	Heterosexual contact with transplant recipient with documented HIV infection	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R24	Heterosexual contact with male with AIDS or documented HIV infection, risk not specified	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R25	Received transfusion of blood/blood components (other than clotting factor)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R26	Received transplant or tissue/organs or artificial insemination	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R27	Injected non-prescription drugs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT,	Required



TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
				LEGACY_PEDIATRIC, BC, DEATH_DOC	
R30	Received clotting factor for hemophilia/coagulation disorder (LEGACY)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R32	Received clotting factor for hemophilia/coagulation disorder (LEGACY)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R33	Received clotting factor for hemophilia/coagulation disorder	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R34	Received transfusion of blood/blood components (other than clotting factor)	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R35	Received transplant of tissue/organs	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R36	Child breastfed/chestfed by birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R37	Child received premasticated/pre- chewed food from birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT,	Required

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
				LEGACY_PEDIATRIC, BC, DEATH_DOC	
R38	Child breastfed/chestfed by non- birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R39	Child received premasticated/pre- chewed food from non-birthing person	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R40	Adult other documented risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R41	Child other documented risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R80	Adult no identified risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
R81	Child no identified risk	YES_NO_UNK_CDC	YES	ACRF, PCRF, LAB_DOC, LEGACY_ADULT, LEGACY_PEDIATRIC, BC, DEATH_DOC	Required
<b>SUBSTANCE_HISTORY</b>	<b>A table that maintains the toxicology data of birthing person and infant during pregnancy, labor and delivery. This information is collected in the Birth History and Birthing Person History sections of Pediatric Case Report Forms (PCRF) documents.</b>				
document_uid	A unique identifier for a document.		YES	PCRF, LEGACY_PEDIATRIC	System

TABLE NAME VARIABLES	DESCRIPTION	Valid data element values (lookup type, reference table, or actual values)	Transfer to CDC	Document Source	Required/Optional
substance_seq	Sequence number.		YES	PCRF, LEGACY_PEDIATRIC	System
doc_belongs_to	Indicates who the substance data belongs to: PERSON or MOTHER.	MOTHER, PERSON	YES	PCRF, LEGACY_PEDIATRIC	System
substance_event_cd	Code to determine if and when substance was tested for use or injection by mother or person.	SUBSTANCE_EVENT_C D	YES	PCRF, LEGACY_PEDIATRIC	System
substance_cd	Substance code used or injected by person.	SUBSTANCE_CD	YES	PCRF, LEGACY_PEDIATRIC	Optional
substance_value	Result value selected.	SUBSTANCE_USE_RESULT SUBSTANCE_SCREEN_RESU LT	YES	PCRF, LEGACY_PEDIATRIC	Optional
substance_detail	User entered substance name when Other (specify) code is chosen.	alphanumeric, NULL, blank	YES	PCRF, LEGACY_PEDIATRIC	Optional
substance_dt	Date of substance screening or use.	YYYYMMDD	YES	PCRF, LEGACY_PEDIATRIC	Optional

## 2024 Standards Evaluation Report (SER)

### Surveillance Program Performance

**Jurisdiction's name:** \_\_\_\_\_

Provide the following:	Name	email
1. Primary Surveillance Contact:		
2. Secondary Surveillance Contact:		
3. S&C Overall Responsible Party:		

#### **A. Death Ascertainment**

- ☐ We are a separately funded city AND all death ascertainment is done at the state level. (*Skip to section B: Laboratory*).
- ☐ We are a state, territory, or separately funded city and perform our own death ascertainment. (*Respond to the questions below and complete the table*).

Ascertain dates of deaths		Linked with deaths occurring through
1	Vital statistics file loaded for deaths <b>OR</b> NDI-Plus early release file loaded for deaths	<input type="checkbox"/> Prohibited
2	SSDMF loaded for deaths	
Ascertain causes of deaths		Linked with deaths occurring through
3	NDI Plus final file with cause-of-death information loaded for deaths	<input type="checkbox"/> Prohibited
4	Vital statistics final file with cause-of-death information loaded for deaths	
Search for potentially unreported HIV cases		Linked with deaths occurring through
5	Searched all vital records deaths mentioning HIV infection and loaded previously unreported cases	

If you did not load all the required files in 1-5 above in accordance with the process standards outlined in the Death Ascertainment Technical Guidance for HIV Surveillance Programs file, please discuss:

- Why you did not load each file in accordance with the process standards.
- Your plan to ensure your program loads each file in the next evaluation period in accordance with the process standards.

Public reporting burden of this collection of information is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0573).

## **B. Laboratory**

1. In 2023, did your surveillance program develop and/or update the list of all laboratories (in jurisdiction and out of jurisdiction) that conducted HIV-related testing for persons who reside in your jurisdiction using a method such as Centers for Medicare and Medicaid Services (CMS) search, or evaluation of your electronic laboratory report (ELR) program baseline spreadsheet?

☐ Yes

- Did you identify new laboratories that conduct HIV testing for persons who reside in your jurisdiction?

☐ Yes

☐ No

- What is the total number of laboratories that report HIV-related test results for persons who reside in your jurisdiction? [Click here to enter text.](#)

○ Please describe how your program obtained this number. [Click here to enter text.](#)

☐ No

2. In 2023 did your surveillance program conduct an assessment of laboratories that conduct HIV-related testing for persons who reside in your jurisdiction? This assessment is to maintain documentation, such as types of tests performed and LOINC usage, by all laboratories that report to your jurisdiction.

☐ Yes

☐ No

3. Are you aware of any laboratory reporting lapses of HIV-related test results for persons who reside within your jurisdiction that resulted in missing laboratory data in your December 2023 data transfer? Please include lapses in laboratory reporting to CDC, including those attributed to the laboratory not reporting test results or because the HL7 reader/transmitter in the health department did not send the results to HIV surveillance.

☐ Yes

Year of specimen collection	Approximately what percentage of your total jurisdiction's laboratory volume is missing for the calendar year indicated?	Approximately what percentage of your total jurisdiction's CD4 results (< 200 and ≥ 200) and viral load results (detectable and undetectable) are missing for the calendar year indicated?
2023*		
2022		

\*At a minimum, lab results through September 2023

☐ No

- In 2023, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? ☐ Yes ☐ No

**C. Pediatric/Perinatal**

<p>Birth Ascertainment</p>	<p>1A. In 2023, did you link women with diagnosed HIV infection reported to the surveillance system to state/local/territory birth certificate data for all 2022 births to identify all perinatally exposed infants with a residence of birth in your jurisdiction?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>1B. If no to 1A, please describe why you did not link with all state/local/territory birth certificate data. [Free text]</p> <p>1C. If yes to 1A, did you enter all information identified from the linkage to state/local/territory birth certificate data into eHARS before your final December 2023 data transfer to CDC?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>1D. If no to 1C, please describe why you did not enter all information identified from the link to state/local/territory birth certificate data into eHARS. [Free text]</p>
<p>Number of perinatally HIV exposed infants for birth year 2022</p>	<p>Provide the number of perinatally HIV exposed infants born in 2022 that were identified through the match to birth certificates. *This should include exposed infants previously known to the HIV surveillance program.</p> <p>Does this match with the number of perinatally exposed infants reported to CDC through your final December 2023 data transfer?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If this does not match, please describe the reasons the numbers do not match (e.g., X perinatally exposed infants reported to health department that were not in the state/local birth certificate data because the infant was a resident of another jurisdiction).</p>
<p>Perinatal HIV Exposure Reporting</p>	<p>Provide percentage of perinatally HIV exposed infants born in 2021 who have HIV infection status determined by 18 months of age (Standard: 85%):</p>

#### **D. Geocoding and Data Linkage**

Submission of Geocoded Data	In 2023, did you submit your geocoded data to CDC, per the Geocoding and Data Linkage Technical Guidance for HIV Surveillance Programs file and the joint MOU?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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#### **E. Cluster Detection**

	Yes	No
1. In 2023, did your program analyze molecular data using CDC-recommended approaches at least monthly to identify HIV transmission clusters and outbreaks?	<input type="checkbox"/>	<input type="checkbox"/>
2. In 2023, did your program conduct time-space analysis using CDC-recommended approaches at least monthly to identify HIV transmission clusters and outbreaks?	<input type="checkbox"/>	<input type="checkbox"/>

#### **F. Submission of Required Outcome Standards with SAS Tables**

**NOTE:** All areas **MUST** run the CDC-supplied SAS programs against the December 2023 frozen eHARS SAS datasets to evaluate and report on your program's outcome standards. **In addition, all SAS table output MUST be included with your SER submission.**

SAS outcome table	Included indicators
Completeness and timeliness tables	<ul style="list-style-type: none"> <li>- Of the expected number of persons whose HIV infection was diagnosed during 2022, at least (<math>\geq</math>) 95% are reported in the local HIV surveillance system, assessed December 2023</li> <li>- Of the expected number of persons whose HIV infection was diagnosed during 2022, at least (<math>\geq</math>) 90% are reported in the local HIV surveillance system within six months of the diagnosis, assessed December 2023</li> </ul>
Intra-jurisdiction case duplication rate table	<ul style="list-style-type: none"> <li>- Of all persons with diagnosed HIV infection who were reported to the local surveillance program through the end of 2022 (cumulative), less than or equal to (<math>\leq</math>) 1% have duplicate case reports, assessed December 2023</li> </ul>
RIDR progress summary tables	<ul style="list-style-type: none"> <li>- Of all pairs on the Routine Interstate Duplicate Review (RIDR) list received January 2023, at least (<math>\geq</math>) 98% were resolved by June 30, 2023</li> <li>- Of all pairs on the Routine Interstate Duplicate Review (RIDR) list received July 2023, at least (<math>\geq</math>) 98% were resolved by December 31, 2023</li> </ul>
CIDR progress summary table	<ul style="list-style-type: none"> <li>- Of all pairs on the Cumulative Interstate Duplicate Review (CIDR) list received January 2018, 100% are resolved by December 31, 2023 <ul style="list-style-type: none"> <li>o Only needs to be submitted by jurisdictions that did <b>not</b> report 100% completion in December 2022: Alabama, Alaska, Arkansas, California, Delaware, District of Columbia, Florida, Georgia, Idaho, Indiana, Los Angeles, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New</li> </ul> </li> </ul>

	Jersey, New Mexico, New York City, Ohio, Pennsylvania, Philadelphia, South Carolina, Texas, Utah, Vermont, Virgin Islands, Wisconsin.
Risk factor ascertainment tables	<ul style="list-style-type: none"> <li>- Of all persons with diagnosed HIV infection who were first entered in the local HIV surveillance system during 2022, at least (<math>\geq</math>) 80% have sufficient risk factor information to be classified into a known transmission category, assessed December 2023</li> </ul>
Lab reporting tables	<ul style="list-style-type: none"> <li>- Of all persons aged 13 years or older with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 85% have a CD4 count or percent based on a specimen collected within one month following HIV diagnosis, assessed December 2023</li> <li>- Of all persons aged 13 years or older with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 85% have a viral load based on a specimen collected within one month following HIV diagnosis, assessed December 2023</li> <li>- Of all laboratory test results entered into eHARS in 2022 for persons with HIV infection diagnosed during 2022, at least 85% were entered into eHARS within 60 days of the specimen collection date, assessed December 2023</li> <li>- Of all persons with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 60% have an analyzable nucleotide sequence, assessed December 2023</li> <li>- Of all persons with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 70% have a known value for previous negative HIV test result, assessed December 2023</li> <li>- Of all persons with HIV infection diagnosed during 2022 who have a previous negative test result, at least (<math>\geq</math>) 50% have a valid date of documented negative test result, assessed December 2023</li> <li>-</li> </ul>
Data quality tables	<ul style="list-style-type: none"> <li>- Of all persons with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 97% have no required fields missing and pass all standard data edit checks, assessed December 2023</li> <li>- Of all persons with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 70% have prior antiretroviral use history, assessed December 2023</li> </ul>
Death ascertainment tables	<ul style="list-style-type: none"> <li>- Of all deaths that occurred during 2021, at least (<math>\geq</math>) 85% have an underlying cause of death, assessed December 2023</li> </ul>
GDL eval outcome tables	<ul style="list-style-type: none"> <li>- Of all persons with HIV infection diagnosed during 2022, at least (<math>\geq</math>) 90% have their residence at diagnosis geocoded to the census tract level, assessed December 2023</li> </ul>
Outcome indicator summary	<ul style="list-style-type: none"> <li>- Summarizes all indicators above (excluding RIDR, CIDR, and GDL)</li> </ul>
<p>Required only for Ending the HIV Epidemic in the US (EHE) priority jurisdictions: (EHE jurisdictions and jurisdictions with EHE counties: Alabama, Arizona, Arkansas, California, Chicago, District of Columbia, Florida, Georgia, Houston, Indiana, Kentucky, Los Angeles, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Jersey, New York City, North Carolina, Ohio, Oklahoma, Philadelphia, Puerto Rico, San Francisco, South Carolina, Tennessee, Texas, Washington)</p>	



PS20_2010 HIV case report timeliness tables	- Of all persons with diagnosed HIV infection whose diagnoses were first entered into the local HIV surveillance system during 2023, at least ( $\geq$ ) 75% were first entered within ( $\leq$ ) 30 days after the date of diagnosis. <sup>+</sup>
PS20_2010 Laboratory results report timeliness tables	- Of all laboratory test results that were entered into the HIV surveillance system during 2023, at least ( $\geq$ ) 75% were entered within ( $\leq$ ) 14 days after the date of specimen collection. <sup>+</sup>

<sup>+</sup>Among cases with person view status = 'A' or 'W'.

## **G. Data Reporting and Dissemination**

<b>In 2023 did you develop and disseminate:</b>	<b>Yes</b>	<b>No</b>
A comprehensive revision of your integrated HIV Epidemiologic Profile?	<input type="checkbox"/>	<input type="checkbox"/>
Updates to the HIV Epidemiologic Profile in the form of updates to core epidemiologic tables and figures, fact sheets, supplemental reports, slide sets, or other publications (but not a comprehensive revision)?	<input type="checkbox"/>	<input type="checkbox"/>
An annual HIV surveillance report?	<input type="checkbox"/>	<input type="checkbox"/>

## **H. Security and Confidentiality**

<b>In 2023:</b>	<b>Yes</b>	<b>No</b>
1. Did your program provide a statement signed by the Overall Responsible Party (ORP) certifying that your program was in <u>full compliance</u> with the <i>Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011)</i> ; hereafter referred to as the NCHHSTP guidelines? Submit your current ORP statement with the SER.	<input type="checkbox"/>	<input type="checkbox"/>
2. Did your program ensure <u>all</u> persons with access to HIV data (including IT personnel) complete an annual security and confidentiality training that is consistent with the NCHHSTP guidelines, sign a confidentiality statement, and store it in the personnel file?	<input type="checkbox"/>	<input type="checkbox"/>
3. Did your program conduct the required annual review of your <u>written</u> security and confidentiality policies and procedures to assess whether changes in legislation or regulations, technology, priorities, personnel, or other situations require updates in policies and procedures?	<input type="checkbox"/>	<input type="checkbox"/>
4. Did your program apply the NCHHSTP guidelines to all sub-contractors and sub-recipients funded through PS18-1802 that have access to or maintain confidential HIV data?	<input type="checkbox"/>	<input type="checkbox"/>
5. Did your program implement secure procedures for data sharing, including Data to Care (D2C) activities, within the context of existing laws, including within your public health program and with external partners (such as sub-recipients)?	<input type="checkbox"/>	<input type="checkbox"/>
6. Did your program implement practices that support secure sharing and use of HIV data across necessary programs within the health department for collaboration with the Medical Monitoring Project (MMP) (if applicable)? <input type="checkbox"/> Not applicable	<input type="checkbox"/>	<input type="checkbox"/>
7. Did any data security breach occur, whether it was of personally identifiable information (PII) or a policy breach? (If yes, please answer a and b below)	<input type="checkbox"/>	<input type="checkbox"/>

a. Did your program ensure documentation and reporting of the data security breach with immediate investigation (regardless of whether there was the release of personal information)?	<input type="checkbox"/>	<input type="checkbox"/>
b. Did your program implement corrective actions to avoid breaches of data security protocol?	<input type="checkbox"/>	<input type="checkbox"/>
8. Did any breach occur that resulted in the release of PII to unauthorized persons? (If yes, please answer a and b below)	<input type="checkbox"/>	<input type="checkbox"/>
a. Did your program ensure that the breach that resulted in the release of PII to unauthorized persons was reported to the ORP, to CDC, and, if warranted to law enforcement agencies?	<input type="checkbox"/>	<input type="checkbox"/>
b. Did your program implement corrective actions to avoid breaches that result in the release of PII to unauthorized persons?	<input type="checkbox"/>	<input type="checkbox"/>

### **I. Cluster Response Performance Measures**

Measure	Standard	Result		
		%	Numerator	Denominator
Testing/re-testing of HIV-negatives and persons with unknown HIV status	For partners of transmission cluster members who were not known to be HIV positive at the time of cluster identification, what percentage were tested or re-tested within 6 months of identification as part of the risk network (for persons identified as part of a risk network in 2022)?			
	Persons with unknown HIV status:	%	n	n
	Persons with negative HIV status:	%	n	n
	Total:	%	n	n
PrEP Referral	For HIV-negative partners of transmission clusters not on PrEP, what percentage were referred for PrEP within 6 months of identification as part of the risk network (for persons identified as part of a risk network in 2022)?	%	n	n
Viral Suppression	Of persons with diagnosed HIV infection who were identified as part of a cluster during 2022 and were not virally suppressed at the time of identification, at least ( $\geq$ ) 60% achieved viral suppression within 6 months of cluster identification, assessed December 2023	Results included in Lab reporting tables generated by the CDC-supplied SAS programs		

For the two Testing/re-testing and PrEP Referral standards above, please briefly discuss what you plan to do in the coming year to improve testing/re-testing and PrEP referral outcomes for persons in clusters and risk networks.

**National HIV Surveillance System (NHSS)**

Attachment 3(f)

Cluster Follow-Up Form

Cluster Report: Follow Up Report (Complete for all clusters, regardless of method of detection)			
Reporting Jurisdiction Name:	0	Low morbidity jurisdiction?	▼
Person Completing Report:		Email address:	
1. Date form completed		2. Local Cluster ID entered into eHARS <b>A local cluster ID must be populated on this form and in eHARS.</b> <b>For molecular clusters, please use the following nomenclature: the two-letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and Secure HIV TRACE cluster ID (e.g., GA_YYYYMM_10-5)</b> <b>For time-space clusters, please use the following nomenclature: the two letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and cluster ID with the initials 'TS' (e.g., GA_YYYYMM_TS789). Please ensure that cluster IDs do NOT contain personal identifiers.</b>	0
3. National Cluster ID (if applicable)	0		
4. Are response activities for this cluster currently ongoing? (If no, DO NOT fill out this form. Complete the Annual/Cluster Closeout Report instead). <div style="float: right;">▼</div>			
5*. Current number of persons in the transmission cluster in your jurisdiction:**			
6. Current number of persons in the risk network in your jurisdiction who are not known to be HIV positive:**			
7. Has testing or re-testing been conducted for any persons who were not known to be HIV positive at the time of identification as part of the risk network?*		▼	
8^a. Of persons who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network, what are the results of testing or re-testing efforts to date?		8a. Total number of persons in the risk network in your jurisdiction tested/re-tested to date:**	
		8b. Total number of persons in the risk network in your jurisdiction who newly tested positive as a result of testing/re-testing efforts:**	
		8c. Total number of persons in the risk network in your jurisdiction newly referred for PrEP:**	
9. Please describe any challenges you have encountered in promoting viral suppression among persons in the transmission cluster, or in conducting testing/re-testing and PrEP referral among persons in the risk network:**			
10. Since the time of cluster detection, have any of the following investigation and/or intervention activities been conducted:			
10a. Partner Services interviews for persons in the transmission cluster who were not previously interviewed?	▼	10b. Partner Services re-interviews for persons in the transmission cluster who were previously interviewed?	▼
10c. Social network interviews and/or testing?	▼	10d. Second-generation interviews (interviews of partners of partners)?	▼
10e. Targeted testing events?	▼	10f. Medical chart reviews?	▼
10g. Qualitative interviews?	▼		
10h. Messaging activities? (If yes, please describe using the box to the right)	▼		
10g. Other activities (If yes, please describe using the box to the right)	▼		
11. What is your current level of concern for this cluster?		▼	
(Provide comments regarding your current level of concern in the box to the right.) Note: Select 'High' if additional response is needed, 'Medium' if additional information about the cluster is needed, or 'Low' if no additional investigation activities are needed at this time.			
12. Additional comments:			

\*This information can be pulled directly from your partner services database and provided as a separate excel attachment rather than reporting separately here, if your system has the functionality to do this.

\*This information can be pulled directly from eHARS and provided as a separate excel attachment rather than reporting separately here.

\*\*For guidance on how to complete these fields for non-molecular clusters, see the Cluster Report Instructions document.

**END OF FOLLOW UP REPORT FORM. If cluster investigation activities are not currently ongoing, please complete the Cluster Closeout Form.**

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0573).

**National HIV Surveillance System (NHSS)**

Attachment 3(g)

Cluster Close-Out Form

Cluster Report: Cluster Annual/Closeout Report (Complete for all clusters, regardless of method of detection)			
Reporting Jurisdiction Name:	0	Low morbidity jurisdiction?	▼
Person Completing Report:		Email address:	
1. Date form completed:		2. Local Cluster ID entered into eHARS <b>A local cluster ID must be populated on this form and in eHARS.</b> <b>For molecular clusters, please use the following nomenclature: the two-letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and Secure HIV TRACE cluster ID (e.g., GA_YYYYMM_10-5)</b> <b>For time-space clusters, please use the following nomenclature: the two letter jurisdiction abbreviation followed by the year and month in which the cluster was first identified and cluster ID with the initials 'TS' (e.g., GA_YYYYMM_TS789). Please ensure that cluster IDs do NOT contain personal identifiers.</b>	0
3. National Cluster ID (if applicable)	0		
4. Are response activities for this cluster currently ongoing?	▼	5. Date cluster investigation and response activities closed: <i>(complete only if the answer to #4 is 'no')</i>	
6. Size of cluster at closeout/current cluster size		Transmission cluster (within your jurisdiction):**	
		Risk network (persons not known to be HIV-infected residing in your jurisdiction):**	
7. Reason(s) for closeout (describe): <i>(complete only if the answer to #4 is 'no')</i>			
8. Since the time of cluster detection, were any of the following investigation and/or intervention activities conducted:			
8a. Partner Services interviews for persons in the transmission cluster who were not previously interviewed?	▼	8b. Partner Services re-interviews for persons in the transmission cluster who were previously interviewed?	▼
8c. Social network interviews and/or testing?	▼	8d. Second-generation interviews (interviews of partners of partners)?	▼
8e. Targeted testing events?	▼	8f. Medical chart reviews?	▼
8g. Qualitative interviews?	▼		
8h. Messaging activities? <i>(If yes, please describe using the box to the right)</i>	▼		
8g. Other activities <i>(If yes, please describe using the box to the right)</i>	▼		
9a*. How many persons in your jurisdiction did not have evidence of viral suppression at the time of identification as part of the cluster?**		9b*. Among persons who did not have evidence of viral suppression at the time of identification as part of the cluster (9a), how many achieved viral suppression within six months?**	
10a*. How many persons in your jurisdiction were HIV-negative or had unknown HIV status at the time of identification as part of the risk network?**		10b*. Of persons who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network (10a), how many were tested/re-tested within 6 months?**	
		10c*. Of persons who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network (10a), how many were tested/re-tested at greater than 6 months?**	
11*. Results of testing and re-testing for persons in 10a: <i>(Report only numeric data for each category below.)</i>			
11a. No. New Positive <sup>1</sup> :		11g. No. Previous Positive <sup>1</sup> :	
11b. Acute: (subset of 11a)		11h. No. Refused testing:	
11c. Recent (not acute): (subset of 11a)		11i. No. Not Located:	
11d. No. Negative:		11j. No. Outside Jurisdiction:	
11e. Referred for PrEP: (subset of 11d)		11k. No. Not tested because person was deceased:	
11f. No. Tested but result Unknown:		11l. No. not tested for other reason:	
<sup>1</sup> These persons should be included as members of the larger transmission cluster			
12a. How many persons in your jurisdiction were HIV-negative and not on PrEP at the time of identification as part of the risk network?**		12b. Of all persons who were HIV-negative and not on PrEP at the time of identification as part of the risk network (12a), how many were screened for PrEP within 6 months?**	
		12c. Of all persons who were screened for PrEP within 6 months(12b), how many were determined to be eligible?**	
		12d. Of all persons who were eligible for PrEP within 6 months (12c), how many were referred?**	
13. What key lessons were learned through the course of investigating this cluster?			

14. Please describe the impact of cluster investigation and response activities on current health department policies and processes (i.e. whether any enhancements were made to regular HIV prevention and treatment processes such as provision of case management services or expansion of PrEP resources, whether communication within the health department or interactions between local and state health departments changed, whether the cluster was used to advocate for policy changes, whether additional resources were required to respond to this particular cluster, etc.).	
15. Briefly describe your current level of concern for this cluster and why ongoing response is still needed. If the cluster response has been closed, instead describe how you will continue monitoring the cluster for future growth.	

^This information can be pulled directly from your partner services database and provided as a separate excel attachment rather than reporting separately here, if your system has the functionality to do this.

\*This information can be pulled directly from eHARS and provided as a separate excel attachment rather than reporting separately here.

\*\*For guidance on how to complete these fields for non-molecular clusters, see the Cluster Report Instructions document.

**END OF CLUSTER ANNUAL/CLOSEOUT REPORT FORM.**

Public reporting burden of this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0573).

## **National HIV Surveillance System (NHSS)**

### **Attachment 4(a)**

Technical Guidance for HIV Surveillance Programs:  
Adult HIV Confidential Case Report Form



# Technical Guidance for HIV Surveillance Programs

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## Adult HIV Confidential Case Report Form

HIV Surveillance Branch  
Atlanta, Georgia

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# Instructions for Completion

## Purpose of Case Report Form

The Adult HIV Confidential Case Report (CDC 50.42A) form (ACRF) is designed to collect information that promotes understanding of HIV infection morbidity and mortality among patients **greater than or equal to 13 years of age** at time of diagnosis. This form reflects data that are required to be collected and some that are recommended or optional. This guidance applies to all HIV infection data collection even if state or local surveillance programs use a different form or medium for HIV case surveillance.

## The Case Report Form in the Context of Document-Based Surveillance

Unlike case-based data management, document-based data management allows all documents to be stored and retained electronically in their original formats. Instead of completing one form for a reported case, fill out the applicable part of the form for each data source contributing information to that HIV case.

## Patients for Whom Form is Indicated

- Each person, greater than or equal to 13 years of age, who meets the HIV infection case definition (available at <https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/>).
- Each person with HIV infection progressing from an earlier or unknown stage to stage 3 (AIDS) diagnosis.
- Each person with HIV infection who has been reported but for whom updated information is available such as new CD4 tests, viral load tests, or drug resistance tests (genotypic) reported from a medical provider, additional risk factor information, updated current address information, or a change in vital status.

If the data are collected electronically and can be imported, recording the information on a hardcopy form is not necessary.

## Definition of Variable Designators

- **Required:** Variables that must be collected by all programs. Please note that for some of these variables there must be a known value reported in order to meet the eligibility criteria for data associated with the patient to be transmitted to the Centers for Disease Control and Prevention (CDC) through the CDC-supplied enhanced HIV/AIDS Reporting System (eHARS). The *eHARS Technical Reference Guide* details the specific variables required to meet the eligibility criteria at the beginning of Chapter 3. The *eHARS Technical Reference Guide* can be accessed through SharePoint: <https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>.
- **Recommended:** Variables that programs are strongly encouraged to collect but are not absolutely required.
- **Optional:** Variables that programs may or may not choose to collect.
- **System generated:** Variables where the value is generated by eHARS.

## Disposition of Form

- The completed form is for state or local health agency use and is not to be sent to CDC. The Pacific Islands are the only jurisdictions that send forms to CDC for data entry and all patient identifiers must be removed before they are sent.
- Data obtained from these forms are entered into standardized computer software provided by the Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC by encrypted electronic

transfer via a secure access management service.

## 1. Patient Identification

### I. Patient Identification (record all dates as mm/dd/yyyy)

*First Name		*Middle Name		*Last Name		Last Name Soundex			
Alternate Name Type (ex: Alias, Married)			*First Name		*Middle Name		*Last Name		
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary			*Current Address, Street				Address Date ____/____/____		
*Phone ( )		City		County		State/Country		*ZIP Code	
*Medical Record Number				*Other ID Type		*Number			

- Patient identifier information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
- 1.1 FIRST NAME (**Required**, applies to health department & health care providers)
    - Enter patient's first name.
  - 1.2 MIDDLE NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's middle name.
  - 1.3 LAST NAME (**Required**, applies to health department & health care providers)
    - Enter patient's last name.
  - 1.4 LAST NAME SOUNDEX (**System generated**)
    - After patient name is entered into eHARS, the software automatically generates this variable by using the patient's last name. After the code is generated, health department staff should fill this field on the form.
    - This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created. You can access the *eHARS Technical Reference Guide* through SharePoint: <https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>
  - 1.5 ALTERNATE NAME TYPE (**Optional**, applies to health department & health care providers)
    - If available, write in the alternate name type (such as Alias, Married).
  - 1.6 ALTERNATE FIRST NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's alternate first name.
  - 1.7 ALTERNATE MIDDLE NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's alternate middle name.
  - 1.8 ALTERNATE LAST NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's alternate last name.
  - 1.9 ADDRESS TYPE (**Required**, applies to health department & health care providers)
    - Select one of the address types for the patient's current address.
  - 1.10 CURRENT ADDRESS, STREET (**Required**, applies to health department & health care providers)
    - Enter the patient's current street address.
  - 1.11 ADDRESS DATE (**Required**, applies to health department & health care providers)
    - Enter the earliest date that the patient was known to be residing at the current address

specified in 1.10. If the patient has resided at an address more than once (and has evidence that they resided elsewhere in between), the address date captured should be the earliest date that the patient moved to the address in the most recent instance.

- You may enter the most recent date the patient was known to be residing at the address in the Comments section. In eHARS, enter the address with the most recent address date on a separate ACRF document on the “Identification” tab.
- Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).

1.12 **PHONE (Required** if patient has a telephone, applies to health department & health care providers)

- Enter patient’s primary area code and telephone number associated with the current address specified in 1.10.

1.13 **CITY (Required**, applies to health department & health care providers)

- Enter patient’s current city.

1.14 **COUNTY (Required**, applies to health department & health care providers)

- Enter patient’s current county.

1.15 **STATE/COUNTRY (Required**, applies to health department & health care providers)

- Enter patient’s current state and country name.

1.16 **ZIP CODE (Required**, applies to health department & health care providers)

- Enter patient’s current zip code.

1.17 **MEDICAL RECORD NUMBER (Optional**, applies to health department & health care providers)

- Enter medical record number of the patient if available.
- This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.
- If the patient has more than one medical record number, enter the number of the primary record that has HIV infection or stage 3 (AIDS) documentation. Additional numbers can be noted in the Comments section annotating which facility is associated with which record number. In eHARS, enter the additional medical record numbers on the “Identification” tab.

1.18–1.19 **OTHER ID TYPE and NUMBER (Optional**, applies to health department & health care providers)

- Enter any additional patient identifier type (such as social security number) and the number of the other identifier. For a list of ID types, please reference the *eHARS Technical Reference Guide*.

## 2. Health Department Use Only

### II. Health Department Use Only (record all dates as mm/dd/yyyy)

Date Received at Health Department ____/____/____	eHARS Document UID	State Number
Reporting Health Dept—City/County	City/County Number	
Document Source	Surveillance Method <input type="checkbox"/> Active <input type="checkbox"/> Passive <input type="checkbox"/> Follow up <input type="checkbox"/> Reabstraction <input type="checkbox"/> Unknown	
Did this report initiate a new case investigation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Report Medium <input type="checkbox"/> 1-Field visit <input type="checkbox"/> 2-Mailed <input type="checkbox"/> 3-Faxed <input type="checkbox"/> 4-Phone <input type="checkbox"/> 5-Electronic transfer <input type="checkbox"/> 6-CD/disk	

2.1 **DATE RECEIVED AT HEALTH DEPARTMENT (Recommended**, applies to health department)

- Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).

2.2 **eHARS DOCUMENT UID (System generated)**

- Enter UID after eHARS generates this variable.

- 2.3 STATE NUMBER (**Required**, applies to health department)
- Enter the assigned state number.
  - Each patient must have a unique state number throughout the course of HIV infection in each state/jurisdiction where they are reported. If the patient was a pediatric “Seroreverter” and was later infected with HIV, the patient must be given two different state numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to Appendix 4.1.4 in Technical Guidance File *Pediatric HIV Confidential Case Report Form* for the definition of a pediatric “Seroreverter”. Jurisdictions must use the “Same as” field on the “Duplicate Review” tab in eHARS to link the two cases. Enter the state number associated with diagnosed HIV infection on the case report form.
  - Assigned numbers **must not** be reused, even if the case is later deleted.
  - This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge state datasets without duplication.
- 2.4 REPORTING HEALTH DEPARTMENT -CITY/COUNTY (**Required**, applies to health department)
- Enter name of city and county of the health department that receives the report from providers of surveillance data.
- 2.5 CITY/COUNTY NUMBER (**Optional**, applies to health department)
- Enter the assigned city/county number.
  - Each patient must have a unique city/county number throughout the course of HIV infection assigned by the separately funded city in which they are reported. If the city/county number is the primary identifier and the patient was a pediatric “Seroreverter” and was later infected with HIV, the patient must be given two different city/county numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to Appendix 4.1.4 in Technical Guidance File *Pediatric HIV Confidential Case Report Form* for the definition of a pediatric “Seroreverter”. If the city/county number is the primary identifier, the jurisdiction must use the “Same as” field on the “Duplicate Review” tab in eHARS to link the two cases. Enter the city/county number associated with diagnosed HIV infection on the case report form.
  - Assigned numbers **must not** be reused, even if the case is later deleted.
- 2.6 DOCUMENT SOURCE (**Required**, applies to health department)
- Enter the code for the document source that provided the information for this report (formerly report source).
  - To clearly identify multiple data sources for a given HIV case (all stages), use a separate case report form for each source.
  - Refer to the *eHARS Technical Reference Guide* for a list of the document source codes available in eHARS.
- 2.7 SURVEILLANCE METHOD (**Required**, applies to health department)
- Enter the method the case report was ascertained.
  - For definitions of active, passive, follow up, re-abstraction see Technical Guidance File *Source Data and Completeness of Reporting*.
- 2.8 DID THIS REPORT INITIATE A NEW INVESTIGATION? (**Optional**, applies to health department)
- Enter whether this case report initiated a new investigation by the health department.
- 2.9 REPORT MEDIUM (**Optional**, applies to health department)
- Health department staff review medical records at provider facilities (i.e., field visits) or

receive information over the telephone, by fax, US mail, or other method, to establish an HIV case and to elicit information for HIV case report forms. The health department can also receive HIV case reports from physicians, laboratories, or other individuals or institutions through electronic transfer or CD/disks. Enter the medium in which the case report was submitted.

### 3. Facility Providing Information

#### III. Facility Providing Information (record all dates as mm/dd/yyyy)

Facility Name			*Phone (     )
*Street Address			
City	County	State/Country	*ZIP Code
<b>Facility Type</b> <u>Inpatient:</u> <u>Outpatient:</u> <input type="checkbox"/> Private physician's office <u>Screening, Diagnostic, Referral Agency:</u> <u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Hospital <input type="checkbox"/> Adult HIV clinic <input type="checkbox"/> CTS <input type="checkbox"/> STD clinic <input type="checkbox"/> Laboratory <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____			
Date Form Completed /    /		*Person Completing Form	*Phone (     )

- Facility information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.

- 3.1 FACILITY NAME (**Recommended**, applies to health department & health care providers)
  - Enter name of the facility providing the information.
  - If data was reported from different facilities, enter name of each on separate forms.
- 3.2 PHONE (**Recommended**, applies to health department & health care providers)
  - Enter facility's current area code and telephone number.
- 3.3 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
  - Enter facility's street address.
- 3.4 CITY (**Recommended**, applies to health department & health care providers)
  - Enter city where facility providing information is located.
- 3.5 COUNTY (**Recommended**, applies to health department & health care providers)
  - Enter county where facility providing information is located.
- 3.6 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
  - Enter state and country name where facility providing information is located.
- 3.7 ZIP CODE (**Recommended**, applies to health department & health care providers)
  - Enter ZIP code where facility providing information is located.
- 3.8 FACILITY TYPE (**Required**, applies to health department & health care providers)
  - Select the type of facility providing information.
  - Refer to the *eHARS Technical Reference Guide* for additional information regarding facility types available in eHARS.
- 3.9 DATE FORM COMPLETED (**Required**, applies to health department & health care providers)
  - Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 3.10 PERSON COMPLETING FORM (**Optional**, applies to health department & health care providers)
  - Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

### 3.11 PHONE (**Recommended**, applies to health department & health care providers)

- Enter the telephone number of the person completing the form.

## 4. Patient Demographics

### IV. Patient Demographics (record all dates as mm/dd/yyyy)

Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown		Country of Birth <input type="checkbox"/> US <input type="checkbox"/> Other/US dependency (specify) _____	
Date of Birth ____/____/____		Alias Date of Birth ____/____/____	
Vital Status <input type="checkbox"/> 1-Alive <input type="checkbox"/> 2-Dead		Date of Death ____/____/____	
State of Death _____			
Gender Identity <input type="checkbox"/> Man <input type="checkbox"/> Woman <input type="checkbox"/> Transgender man <input type="checkbox"/> Transgender woman			
<input type="checkbox"/> Additional gender identity (specify) _____			
<input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown			
Date Identified ____/____/____			
Sexual Orientation <input type="checkbox"/> Straight or heterosexual <input type="checkbox"/> Lesbian or gay <input type="checkbox"/> Bisexual			
<input type="checkbox"/> Additional sexual orientation (specify) _____			
<input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown			
Date Identified ____/____/____			
Ethnicity <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino <input type="checkbox"/> Unknown		Expanded Ethnicity _____	
Race (check all that apply) <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American		Expanded Race _____	
<input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown			

### 4.1 SEX ASSIGNED AT BIRTH (**Required**, applies to health department & health care providers)

- Select patient's sex assigned at birth.
- If search for this datum was completed and sex assigned at birth could not be assigned as "Male" or "Female", select "Unknown".

### 4.2 COUNTRY OF BIRTH (**Recommended**, applies to health department & health care providers)

- Select applicable response.
- For patients born in US minor outlying areas, specify the name of the US dependency from the following table:

US Dependencies	
Baker Island	Midway Islands
Howland Island	Navassa Island
Jarvis Island	Palmyra Atoll
Johnston Atoll	Wake Island
Kingman Reef	

- For patients born in any other area outside of the US and US minor outlying areas, specify the country/US dependency name.

### 4.3 DATE OF BIRTH (**Required**, applies to health department & health care providers)

- Enter patient's date of birth in mm/dd/yyyy format using ".." for unknown values (e.g., 03/../2011).

### 4.4 ALIAS DATE OF BIRTH (**Optional**, applies to health department & health care providers)

- If available, enter the alias date of birth in mm/dd/yyyy format using ".." for unknown values (e.g., 03/../2011).

### 4.5 VITAL STATUS (**Required**, applies to health department & health care providers)

- Enter vital status at time of this report.
- For further guidance on death ascertainment, see Technical Guidance File *Death Ascertainment*.

### 4.6 DATE OF DEATH (**Required**, if applicable, applies to health department & health care providers)



- If patient is deceased, enter date of death in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
  - For further guidance on death ascertainment, see Technical Guidance File *Death Ascertainment*.
- 4.7 STATE OF DEATH (**Required**, if applicable, applies to health department & health care providers)
- If patient is deceased, enter the state name where the death occurred. If the death occurred outside of the US, enter “Foreign Country”.
- 4.8 GENDER IDENTITY and DATE IDENTIFIED (**Required**, applies to health department & health care providers)
- Enter the gender identity of the patient.
  - If the patient’s stated gender identity differs from the selections provided or the patient’s stated gender identity at a point in time includes more than one of the selections provided, select “Additional gender identity” and specify the gender identity or gender identities.
  - If documented that the patient declined to provide their gender identity, select “Declined to answer”.
  - If search for this datum was completed and gender identity could not be determined or if gender identity was documented to be unknown, select “Unknown”.
  - Refer to the lookup codes in the *eHARS Technical Reference Guide* for gender identity values available in eHARS.
  - For date identified, please enter the date the patient indicated identifying as the selected gender identity, if documented. If this date is unknown, enter the date of service (e.g., medical appointment, partner services interview) for when the information on gender identity was obtained. If that date is unknown, enter the most recent date of service. You may also enter the most recent date associated with the patient’s gender identity in the Comments section. In eHARS, enter the gender identity value associated with the most recent date on a separate ACRF document on the “Demographics” tab. Record the date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
  - If the patient’s gender identity has changed over time, record the other gender identities and associated dates identified in the Comments section. In eHARS, enter each additional value on separate ACRF documents on the “Demographics” tab.
- 4.9 SEXUAL ORIENTATION and DATE IDENTIFIED (**Required**, applies to health department & health care providers)
- Enter sexual orientation of the patient.
  - If the patient’s stated sexual orientation differs from the selections provided or the patient’s stated sexual orientation at a point in time includes more than one of the selections provided, select “Additional sexual orientation” and specify the sexual orientation or sexual orientations.
  - If documented that the patient declined to provide their sexual orientation, select “Declined to answer”.
  - If search for this datum was completed and sexual orientation could not be determined or if the sexual orientation was documented to be unknown, select “Unknown”.
  - Refer to the lookup codes in the *eHARS Technical Reference Guide* for sexual orientation values available in eHARS.
  - For date identified, please enter the date the patient indicated identifying as the selected sexual orientation, if documented. If this date is unknown, enter the date of service for when the information on sexual orientation was obtained. If that date is unknown, enter the most recent date of service. You may also enter the most recent date associated with the patient’s

sexual orientation in the Comments section. In eHARS, enter the sexual orientation value associated with the most recent date on a separate ACRF document on the “Demographics” tab. Record it in mm/dd/yyyy format using “..” for unknown values (e.g., 03../2011).

- If the patient’s sexual orientation has changed over time, record other sexual orientations and associated dates identified in the Comments section. In eHARS, enter each additional value on separate ACRF documents on the “Demographics” tab.

4.10 **ETHNICITY (Required, applies to health department & health care providers)**

- If search for this datum was completed and ethnicity could not be determined or if ethnicity was documented to be unknown, select “Unknown”.
- If no search for this datum was completed, leave this field blank.
- Regardless of the availability of data on race, collect data on ethnicity.
- As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic/Latino, Not Hispanic/Latino) for a person be collected as separate variables.
- A wide variety of ethnicities may be selected from values available in eHARS. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.

4.11 **EXPANDED ETHNICITY (Optional, if applicable, applies to health department & health care providers)**

- Enter more specific ethnicity information for greater detail such as “Hispanic or Latino.Cuban” or “Hispanic or Latino.Puerto Rican”.
- Refer to the *eHARS Technical Reference Guide* for listing of expanded ethnicity.

4.12 **RACE (Required, applies to health department & health care providers)**

- Select patient’s race even if information was submitted for ethnicity.
- Select more than one race if applicable.
- If no race information is available, select “Unknown”.
- As of January 2003, the US Office of Management and Budget (OMB) required that systems collect multiple races for a person (OMB Policy Directive 15 updated standards); at a minimum, collect data on the following five categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.
- Refer to the *eHARS Technical Reference Guide* for further details.

4.13 **EXPANDED RACE (Optional, if applicable, applies to health department & health care providers)**

- Enter more specific race information for greater detail such as “American Indian or Alaska Native.Navajo” or “White.Middle Eastern or North African”.
- Refer to the *eHARS Technical Reference Guide* for listing of expanded race.

## 5. Residence at Diagnosis

**V. Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)**

<b>Address Event Type</b> (check all that apply to address below) <input type="checkbox"/> Residence at HIV diagnosis <input type="checkbox"/> Residence at stage 3 (AIDS) diagnosis <input type="checkbox"/> Check if <u>SAME</u> as current address			
<b>Address Type</b> <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary			
<b>*Street Address</b>			
<b>City</b>	<b>County</b>	<b>State/Country</b>	<b>*ZIP Code</b>

- Residence information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
- Refer to [Appendix 5.0](#) for further guidance.
- If patient’s residence at HIV diagnosis and stage 3 (AIDS) diagnosis are different, enter the address information associated with the stage 3 (AIDS) diagnosis in the Comments section.

In eHARS, enter the address information associated with stage 3 (AIDS) diagnosis on the “Demographics” tab with the applicable address event type.

- 5.1 ADDRESS EVENT TYPE (**Required**, applies to health department & health care providers)
  - Select the address event type for the patient’s residence at diagnosis.
  - If the patient’s residence at HIV diagnosis and stage 3 (AIDS) diagnosis was the same, you may check both.
- 5.2 ADDRESS TYPE (**Required**, applies to health department & health care providers)
  - Select one of the address types for the patient’s address of residence at diagnosis.
- 5.3 STREET ADDRESS (**Required**, applies to health department & health care providers)
  - Enter street address of residence at diagnosis.
- 5.4 CITY (**Required**, applies to health department & health care providers)
  - Enter city of residence at diagnosis.
- 5.5 COUNTY (**Required**, applies to health department & health care providers)
  - Enter county of residence at diagnosis.
- 5.6 STATE/COUNTRY (**Required**, applies to health department & health care providers)
  - Enter the state and country name of residence at diagnosis.
- 5.7 ZIP CODE (**Required**, applies to health department & health care providers)
  - Enter the ZIP code of residence at diagnosis.

## 6. Facility of Diagnosis

### VI. Facility of Diagnosis (add additional facilities in Comments)

Diagnosis Type (check all that apply to facility below) <input type="checkbox"/> HIV <input type="checkbox"/> Stage 3 (AIDS) <input type="checkbox"/> Check if <u>SAME</u> as facility providing information			
Facility Name			*Phone (    )
*Street Address			
City	County	State/Country	*ZIP Code
Facility Type <u>Inpatient:</u> <input type="checkbox"/> Hospital <u>Outpatient:</u> <input type="checkbox"/> Private physician’s office <u>Screening, Diagnostic, Referral Agency:</u> <u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Adult HIV clinic <input type="checkbox"/> CTS <input type="checkbox"/> STD clinic <input type="checkbox"/> Laboratory <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____			
*Provider Name		*Provider Phone (    )	Specialty

- Facility information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
  - If the patient’s HIV diagnosis and stage 3 (AIDS) diagnosis occurred at different facilities, enter the stage 3 (AIDS) facility information in the Comments section. In eHARS, enter the facility information associated with stage 3 (AIDS) diagnosis on the “Facility” tab with the applicable diagnosis type.
- 6.1 DIAGNOSIS TYPE (**Recommended**, applies to health department & health care providers)
    - Enter the diagnosis type that corresponds to the facility of diagnosis being reported.
  - 6.2 FACILITY NAME (**Recommended**, applies to health department & health care providers)
    - Enter name of the facility where patient was first diagnosed which corresponds with the “Diagnosis Type” reported in 6.1.
    - Refer to [Appendix 6.2](#) for further details.
  - 6.3 PHONE (**Recommended**, applies to health department & health care providers)
    - Enter area code and telephone number of the facility of diagnosis.
  - 6.4 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
    - Enter street address of the facility of diagnosis.

- 6.5 CITY (**Recommended**, applies to health department & health care providers)
- Enter city of the facility of diagnosis.
- 6.6 COUNTY (**Recommended**, applies to health department & health care providers)
- Enter county of the facility of diagnosis.
- 6.7 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
- Enter state and country name of the facility of diagnosis.
- 6.8 ZIP CODE (**Recommended**, applies to health department & health care providers)
- Enter ZIP code where the facility of diagnosis is located.
- 6.9 FACILITY TYPE (**Required** applies to health department & health care providers)
- Select the type of facility of diagnosis.
  - Refer to the *eHARS Technical Reference Guide* for listing of facility types.
- 6.10 PROVIDER NAME (**Recommended**, applies to health department & health care providers)
- Enter provider's name where the patient was first diagnosed which corresponds with the "Diagnosis Type" reported in 6.1.
- 6.11 PROVIDER PHONE (**Recommended**, applies to health department & health care providers)
- Enter area code and telephone number for provider selected in 6.10.
- 6.12 SPECIALTY (**Optional**, applies to health department & health care providers)
- Enter provider's specialty for provider selected in 6.10.

## 7. Patient History

### VII. Patient History (respond to all questions) (record all dates as mm/dd/yyyy) ☐ Pediatric Risk (enter in Comments)

After 1977 and before the earliest known diagnosis of HIV infection, this patient had:		
Sex with male	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
Sex with female	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
Injected nonprescription drugs	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
Received clotting factor for hemophilia/coagulation disorder Specify clotting factor: _____ Date received ____/____/____	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>HETEROSEXUAL relations with any of the following:</b>		
HETEROSEXUAL contact with person who injected drugs	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with bisexual male	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
First date received ____/____/____ Last date received ____/____/____		
Received transplant of tissue/organs or artificial insemination	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
Worked in a healthcare or clinical laboratory setting	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown
If occupational exposure is being investigated or considered as primary mode of exposure, specify occupation and setting: _____		
Other documented risk (include detail in Comments)	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Unknown

- These data yield information about how patients may have acquired their infections.
  - Check box at the top of this section if the risk factor was a pediatric risk factor and enter additional information in the Comments section. In eHARS, on the ACRF select the "Show Pediatric Risk Factors" check box on the "History tab to display and record the pediatric risk factor.
  - Respond to each risk factor, selecting "Yes" for all factors that apply; "No" for those

that do not apply (only select “No” if medical record specifically states this is not a risk factor); and “Unknown” for those for which investigation failed to yield an answer. If an investigation for a particular item was not performed, then you should leave it blank. Collect data about risk factors that occurred before the earliest known diagnosis of HIV infection. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.

- See [Appendix 7.0](#) for further guidance on risk factor ascertainment.

7.1 SEX WITH MALE (**Required**, applies to health department & health care providers)

- Select applicable response based on the partner’s sex assigned at birth. If search for this datum was completed and the partner’s sex assigned at birth cannot be determined, select “Unknown”.
- Some examples of information from the medical record which would strongly indicate sex with a male are below.
  - For male patient:
    - Married to or divorced from a male;
    - Rectal gonorrhea.
  - For female patient:
    - Married to or divorced from a male;
    - Boyfriend referenced in the medical record;
    - Living with a male partner;
    - History of pregnancy;
    - History of another sexually transmitted infection (in addition to HIV);
    - Sex worker (either current or in the past).

7.2 SEX WITH FEMALE (**Required**, applies to health department & health care providers)

- Select applicable response based on the partner’s sex assigned at birth. If search for this datum was completed and the partner’s sex assigned at birth cannot be determined, select “Unknown”.
- Some examples of information from the medical record which would strongly indicate sex with a female are below.
  - For male patient:
    - Married to or divorced from a female;
    - Has a biological child
  - For female patient:
    - Married to or divorced from a female.

7.3 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)

- Select applicable response.
- Select “Yes” if the patient injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the patient was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).

7.4-7.6 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER, SPECIFY CLOTTING FACTOR, and DATE RECEIVED (**Required**, applies to health department & health care providers)

- Select applicable response.
- “Coagulation disorder” or “hemophilia” refers only to a disorder of a clotting factor; factors are any of the circulating proteins named Factor I through Factor XII. These disorders include Hemophilia A and Von Willebrand’s disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).

- This risk factor is generally documented in the history and physical section of the patient’s medical chart.
- They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
- If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select “No”.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and cases of public health importance (COPHI).
- Alert state/local COPHI coordinator if select “Yes”.
- If “Yes”, specify the clotting factor and enter date received. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).

## 7.7 HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:

- This section, addressed at 7.7.1–7.7.6, relates to ascertainment of risk among persons who had heterosexual contact (had sex with) with the case patient.
- Heterosexual contact is defined as the patient having sexual contact with a partner whose sex assigned at birth is different from the patient’s sex assigned at birth.
- Verification of sex partner’s HIV infection status is not necessary.

### 7.7.1 PERSON WHO INJECTED DRUGS (**Required**, applies to health department & health care providers)

- Select applicable response.
- Select “Yes” if the partner injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the partner was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).

### 7.7.2 BISEXUAL MALE (**Required**, applies to health department & health care providers)

- Select applicable response only if patient’s sex assigned at birth is female. “Yes” should be selected only if the partner’s sex assigned at birth is male and there is evidence that the partner also had sex with another person whose sex assigned at birth was male.

### 7.7.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)

- Select applicable response.
- Refer to 7.4-7.6 for additional information.

### 7.7.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)

- Select applicable response.
- Consider documenting the reason for transfusion in the Comments section. In eHARS, enter on the “Comments” tab.

### 7.7.5 TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)

- Select applicable response.
- Consider documenting the reason for transplant in the Comments section. In eHARS, enter on the “Comments” tab.

### 7.7.6 PERSON WITH DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to health department & health care providers)

- Select applicable response.
- Select “Yes” only if HETEROSEXUAL sex partner is known to be HIV positive and



that partner's risk factor for HIV is unknown.

7.8-7.10 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR), FIRST DATE RECEIVED, and LAST DATE RECEIVED (**Required**, applies to health department & health care providers)

- Select applicable response.
- Blood is defined as a circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets).
- Blood components that can be transfused include erythrocytes, leukocytes, platelets, and plasma.
- It is often helpful to document the reason for the transfusion in the Comments section. In eHARS, enter on the "Comments" tab.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and COPHI.
- If the last transfusion was after March 1985, then alert state/local COPHI coordinator.
- If "Yes", enter the dates first and last received in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03../2011).

7.11 RECEIVED TRANSPLANT OF TISSUE/ORGANS OR ARTIFICIAL INSEMINATION (**Required**, applies to health department & health care providers)

- Select applicable response.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and COPHI.
- Alert the state/local COPHI coordinator if select "Yes".

7.12-7.13 WORKED IN HEALTH CARE OR CLINICAL LABORATORY SETTING and IF OCCUPATIONAL EXPOSURE IS BEING INVESTIGATED OR CONSIDERED AS PRIMARY MODE OF EXPOSURE, SPECIFY OCCUPATION AND SETTING (**Required** applies to health department & health care providers)

- Select applicable response.
- Investigate apparent occupational exposures to determine if this was the only risk factor present.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and COPHI.
- Alert state/local COPHI coordinator if select "Yes".
- If "Yes", specify occupation and setting.

7.14 OTHER DOCUMENTED RISK (**Required** applies to health department & health care providers)

- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on unusual transmission history that could be considered as potential COPHI.
- Select applicable response.
- Document details of the risk information in the Comments section. In eHARS, enter on the "Comments" tab.

## 8. Clinical: Acute HIV Infection and Opportunistic Illnesses

### VIII. Clinical: Acute HIV Infection and Opportunistic Illnesses (record all dates as mm/dd/yyyy)

<b>Suspect acute HIV infection?</b> If YES, complete the two items below; enter documented negative HIV test result data in Laboratory Data section, and enter patient or provider report of previous negative HIV test result in HIV Testing History section. Clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)? Date of sign/symptom onset ____/____/____ Other evidence suggestive of acute HIV infection? If YES, describe: _____ Date of evidence ____/____/____		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
<b>Opportunistic Illnesses</b>					
<b>Diagnosis</b>	<b>Dx Date</b>	<b>Diagnosis</b>	<b>Dx Date</b>	<b>Diagnosis</b>	<b>Dx Date</b>
Candidiasis, bronchi, trachea, or lungs		Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis		M. tuberculosis, pulmonary <sup>1</sup>	
Candidiasis, esophageal		Histoplasmosis, disseminated or extrapulmonary		M. tuberculosis, disseminated or extrapulmonary <sup>1</sup>	
Carcinoma, invasive cervical		Isosporiasis, chronic intestinal (>1 mo. duration)		Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Coccidioidomycosis, disseminated or extrapulmonary		Kaposi's sarcoma		Pneumocystis pneumonia	
Cryptococcosis, extrapulmonary		Lymphoma, Burkitt's (or equivalent)		Pneumonia, recurrent, in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, immunoblastic (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, primary in brain		Salmonella septicemia, recurrent	
Cytomegalovirus retinitis (with loss of vision)		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary		Toxoplasmosis of brain, onset at >1 mo. of age	
HIV encephalopathy				Wasting syndrome due to HIV	

<sup>1</sup>If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:

#### 8.1 CLINICAL: ACUTE HIV INFECTION

- Collection of acute HIV infection information is **recommended** for all state and local health departments.
- The purpose of this section is to facilitate the identification of persons with acute HIV infection for more urgent follow-up, as applicable according to state and local health department policies and practices. Acute HIV infections are more transmissible than other HIV infections. Clinical criteria for acute HIV infection may overlap the surveillance case definition of stage 0 (early HIV infection).
  - Persons more likely to have acute HIV infection may be identified by a shorter interval (relative to the stage-0-defining period of up to 180 days) between a negative or indeterminate HIV test result and the first HIV-positive test result associated with diagnosis. The maximum length of the interval between these two tests could range from 30 to 90 days and may be determined locally.
  - This section includes clinical (non-laboratory) data to supplement the laboratory-based criteria for stage 0 to identify persons with probable or possible acute HIV infection for follow-up as applicable.
- These variables indicative of probable or possible acute HIV infection may be used separately or in combination with the eHARS stage 0 variable (*stage\_zero\_dx*) to inform epidemiologic analyses.
- For further information about acute HIV infection, see Technical Guidance File *Early HIV Infection, HIV-2, and Other Diagnostic Considerations*.

##### 8.1.1 SUSPECT ACUTE HIV INFECTION? (**Recommended**, applies to health department & health care providers)

- This variable is meant to encompass all sources of available information that might indicate acute HIV, and its use could vary with each state or local jurisdiction's policies and practices. For further information about the sources of information, see Technical Guidance File *Source Data and Completeness of Case Reporting*. The information about acute HIV status could include laboratory-documented evidence from the laboratory-based HIV testing algorithm, such as having a positive initial immunoassay result followed by a negative or indeterminate type-differentiating supplemental test and a subsequent positive NAT; or it could include a laboratory-documented or patient or provider reported history of a previous negative HIV test before diagnosis. Additionally, it could include information from a provider reporting



that the patient had acute HIV, or include provider notes about symptoms of acute HIV, or there may have been clear information about a specific exposure that occurred just before diagnosis and no possibility of exposure prior to that specific occurrence.

- Select “Yes” if there is any evidence to suspect that the patient had acute HIV infection at diagnosis. If “Yes” is selected, then ensure the following:
  - Complete the items below for “Clinical signs/symptoms consistent with acute retroviral syndrome” and “Other evidence suggestive of acute HIV infection”.
  - Documented negative or indeterminate HIV test results that include the type of test and date should be entered in the Laboratory Data section.
  - Patient or provider reports of a previous negative HIV test should be entered in the HIV Testing History section.
- “No” indicates sufficient evidence that the patient did not have acute HIV infection at diagnosis.
- “Unknown” indicates there is insufficient evidence to indicate whether the patient had acute HIV infection at diagnosis, after searching for the information, consulting with the provider, or asking the patient.

#### 8.1.2 CLINICAL SIGNS/SYMPTOMS CONSISTENT WITH ACUTE RETROVIRAL SYNDROME (**Recommended**, applies to health department & health care providers)

- This field is intended for collecting evidence of the clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, and/or lymphadenopathy; generally, two or more symptoms such as these are present). For a more complete list of the clinical symptoms associated with acute HIV, refer to [Appendix 8.1.2](#).
- This information would typically be found in the clinical record and could be explicitly stated as acute retroviral syndrome (ARS) or primary HIV infection (PHI), or that the provider suspects acute infection, or there could just be a description of the case’s presenting symptoms at the time of HIV testing together with plausible information about a recent HIV exposure. Ideally, ARS or PHI would be determined by a clinician who has ruled out other illness.
- If it is unclear whether any symptoms are related to acute HIV, consult with medical professionals.
- Select “Yes” if there is clear evidence that the patient had clinical signs/symptoms consistent with acute retroviral syndrome.
- “No” indicates sufficient evidence that the patient did not clinical signs/symptoms consistent with acute retroviral syndrome.
- “Unknown” indicates there is insufficient evidence to indicate whether the patient had clinical signs/symptoms consistent with acute retroviral syndrome, after searching for the information, consulting with the provider, or asking the patient.

#### 8.1.3 DATE OF SIGN/SYMPTOM ONSET (**Recommended**, applies to health department & health care providers)

- Record the earliest date of sign/symptom onset.
- Enter date in *mm/dd/yyyy* format. If day is unknown, use “..” for the unknown value (e.g., 03/./2017).

#### 8.1.4 OTHER EVIDENCE SUGGESTIVE OF ACUTE HIV INFECTION? (**Recommended**, applies to health department & health care providers)

- Select “Yes” if there is any other evidence of acute HIV that is not based on diagnostic HIV-related test information or signs/symptoms of acute HIV. An example would be a patient who had a high viral load (>500,000 copies/mL) at or within 6 weeks after diagnosis, or a clear exposure to HIV that occurred just before diagnosis

in the setting where an earlier source of infection is unlikely (e.g., a rape or an occupational exposure).

- Viral load data should be entered in the Laboratory Data section.
- Note that an occupational exposure would also be followed up as a COPHI.
- “No” indicates sufficient information to indicate no other evidence of acute HIV infection.
- “Unknown” indicates there is insufficient evidence to indicate whether there was any other evidence of acute HIV infection, after searching for the information, consulting with the provider, or asking the patient.

8.1.5 OTHER EVIDENCE SUGGESTIVE OF ACUTE HIV INFECTION (SPECIFY)  
(**Recommended**, applies to health department & health care providers)

- Enter a brief description of the exposure leading to the determination of a presumptive acute HIV diagnosis, (e.g., “High viral load—980,000 copies/mL”, or “Patient raped in Feb, HIV diagnosis in March”).

8.1.6 DATE OF EVIDENCE (**Recommended**, applies to health department & health care providers)

- Record the date associated with the other evidence.
- Enter date in *mm/dd/yyyy* format. If day is unknown, use “..” for the unknown value (e.g., 03/./2017).

8.2 CLINICAL: OPPORTUNISTIC ILLNESSES

8.2.1–8.2.26 (**Optional**, applies to health department & health care providers)

- Select all that apply and enter diagnosis dates. Enter date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03/./2011).
- For additional information, refer to the most recent case definition for HIV infection (available at <https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/>).

8.2.27 RVCT CASE NUMBER (**Optional**, applies to health department & health care providers)

- If this patient has a verified case of tuberculosis (TB), health department staff enter the nine-digit alphanumeric code from the TB case report or TB data management system. Providers in the private and public sectors diagnosing tuberculosis in their stage 3 (AIDS) patients may get this number from TB surveillance staff.

## 9. Laboratory Data

### IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)

<b>HIV Immunoassays</b>	
TEST <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-2 IA	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Collection Date ____/____/____
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	

### IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy) (cont)

<b>TEST</b> <input type="checkbox"/> HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab)	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result Overall: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	Collection Date ____/____/____
Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive HIV-1/2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <sup>3</sup> Overall interpretation: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Index Value _____	Collection Date ____/____/____
Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Not reportable due to high Ab level Index Value _____	
HIV-1 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated Index Value _____	
HIV-2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated Index Value _____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1/2 type-differentiating immunoassay (supplemental) (differentiates between HIV-1 Ab and HIV-2 Ab)	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <sup>4</sup> Overall interpretation: <input type="checkbox"/> HIV positive, untypable <input type="checkbox"/> HIV-1 positive with HIV-2 cross-reactivity <input type="checkbox"/> HIV-2 positive with HIV-1 cross-reactivity	
<input type="checkbox"/> HIV negative <input type="checkbox"/> HIV indeterminate <input type="checkbox"/> HIV-1 indeterminate <input type="checkbox"/> HIV-2 indeterminate <input type="checkbox"/> HIV-1 positive <input type="checkbox"/> HIV-2 positive	
Analyte results: HIV-1 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate Collection Date ____/____/____	
HIV-2 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 WB	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Collection Date ____/____/____
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>HIV Detection Tests</b>	
<b>TEST</b> <input type="checkbox"/> HIV-1/2 RNA NAAT (Qualitative)	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> Both (HIV-1 and HIV-2) <input type="checkbox"/> HIV, not differentiated (HIV-1 or HIV-2) <input type="checkbox"/> Neither (negative)	Collection Date ____/____/____
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 RNA NAAT (Qualitative and Quantitative)	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result Qualitative: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	Collection Date ____/____/____
Analyte results: HIV-1 Quantitative: <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit	
Copies/mL _____	Log _____
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-1 culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-2 culture	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Collection Date ____/____/____
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>TEST</b> <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative) <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Quantitative)	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
Result <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit <input type="checkbox"/> Not detected	Copies/mL _____ Log _____
Collection Date ____/____/____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>Drug Resistance Tests (Genotypic)</b>	
<b>TEST</b> <input type="checkbox"/> HIV-1 Genotype (Unspecified)	
Lab Name _____	Test Brand Name/Manufacturer _____
Provider Name _____	Facility Name _____
Collection Date ____/____/____	
<b>Immunologic Tests (CD4 count and percentage)</b>	
CD4 count _____ cells/ $\mu$ L	CD4 percentage _____ %
Collection Date ____/____/____	
Test Brand Name/Manufacturer _____	Lab Name _____
Facility Name _____	Provider Name _____
<b>Documentation of Tests</b>	
Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
If YES, provide specimen collection date of earliest positive test result for this algorithm ____/____/____	
Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.	
Is earliest evidence of HIV infection diagnosis documented by a physician rather than by laboratory test results? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
If YES, provide date of diagnosis by physician ____/____/____	
Date of last documented negative HIV test result (before HIV diagnosis date) ____/____/____	
Specify type of test: _____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	

<sup>2</sup>Results not directly observed by a provider should be recorded in HIV Testing History.

<sup>3</sup>Complete the overall interpretation and the analyte results.

<sup>4</sup>Always complete the overall interpretation. Complete the analyte results when available.

- Throughout this section, “Collection Date” refers to the date when the specimen was collected or drawn. Enter collection dates in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
- Record all laboratory test results. Include results all diagnostic tests, viral load tests, CD4 tests, and drug resistance tests (genotypic) where possible. Where the number of test results exceeds the number of fields available on the form, record such results in the Comments section. In eHARS, enter the additional test results on the “Lab Data” tab with the applicable test type.
- Include tests with negative or indeterminate results that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). For information on the current HIV diagnostic testing algorithm, please refer to <https://stacks.cdc.gov/view/cdc/50872>.
- In the absence of laboratory tests, record HIV infection or stage 3 (AIDS) diagnostic evidence documented in the chart by a physician.

## 9.1 HIV IMMUNOASSAYS (IA)

- Assuming active case finding, review patient’s chart and laboratory reports for the earliest date of documented HIV positivity.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
  - Enter specimen collection date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
- Enter testing option for all tests. (**Optional**, applies to health department & health care providers)
  - Enter “Point-of-care test by provider” if the test was performed by the provider either in a healthcare setting or other testing venue.
  - Enter “Self-test, result directly observed by provider” if the test was performed by the patient but directly observed by a provider (including via a telemedicine appointment).
  - Enter “Lab-test, self-collected sample” if the patient collected the sample (blood or oral fluid) and sent it to the laboratory for testing.

### 9.1.1 HIV-1 IA

- Enter result and collection date of first HIV-1 IA. (**Required**, applies to health department & health care providers)
- “Positive IA” means a result of repeatedly reactive on a single sample.

### 9.1.2 HIV-1/2 IA

- Enter result and date of first HIV-1/2 IA. (**Required**, applies to health department & health care providers)
- “Positive IA” means a result of repeatedly reactive on a single sample.

### 9.1.3 HIV-1/2 AG/AB

- Enter result and collection date of first HIV-1/2 combination IA test. (**Required**, applies to health department & health care providers)
- “Positive IA” means a result of repeatedly reactive on a single sample.

### 9.1.4 HIV-2 IA

- Enter result and collection date of first HIV-2 IA. (**Required**, applies to health

- department & health care providers)
  - “Positive IA” means a result of repeatedly reactive on a single sample.
- 9.1.5 HIV-1/2 AG/AB-DIFFERENTIATING IMMUNOASSAY
  - Enter collection date of first HIV-1/2 Ag/Ab-Differentiating IA. (**Required**, applies to health department & health care providers)
  - Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
  - Record the result for each analyte (HIV-1 Ag and HIV-1/2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1/2 Ab result. (**Required**, applies to health department & health care providers)
- 9.1.6 HIV-1/2 AG/AB AND TYPE-DIFFERENTIATING IMMUNOASSAY
  - Enter collection date of first HIV-1/2 Ag/Ab and Type-Differentiating IA. (**Required**, applies to health department & health care providers)
  - Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
  - If provided, enter index value for the overall interpretation. (**Optional**, applies to health department & health care providers)
  - Record the result for each analyte (HIV-1 Ag and HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)
  - Enter the index value for each analyte. (**Optional**, applies to health department & health care providers)
- 9.1.7 HIV-1/2 TYPE-DIFFERENTIATING IMMUNOASSAY (supplemental)
  - Enter collection date of first HIV-1/2 Type-Differentiating IA. (**Required**, applies to health department & health care providers)
  - Enter the overall interpretation of the test. (**Required**, applies to health department & health care providers)
  - Record the result for each analyte (HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)
- 9.1.8 HIV-1 WESTERN BLOT
  - Enter the result and collection date of first HIV-1 western blot. (**Required**, applies to health department & health care providers)
  - Western blot banding patterns should be interpreted according to the CDC/Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) recommendations *Interpretation and use of the western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections*. MMWR Suppl. 1989 Jul 21;38(7):1-7. PMID: 2501638.
- 9.1.9 HIV-1 IFA
  - Enter the result and collection date of first HIV-1 IFA. (**Required**, applies to health department & health care providers)
- 9.1.10 HIV-2 WESTERN BLOT
  - Enter the result and collection date of first HIV-2 western blot. (**Required**, applies to health department & health care providers)
- 9.2 HIV DETECTION TESTS
  - All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as an immunoassay or western blot establish the presence of the immune system’s

response to the pathogen (i.e., HIV antibodies).

- Assuming active case finding, review patient's chart and laboratory reports for the earliest date of documented HIV positivity.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
  - Enter specimen collection date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
- Enter testing option for all tests. (**Optional**, applies to health department & health care providers)
  - Enter “Point-of-care test by provider” if the test was performed by the provider either in a healthcare setting or other testing venue.
  - Enter “Self-test, result directly observed by provider” if the test was performed by the patient but directly observed by a provider (including via a telemedicine appointment).
  - Enter “Lab-test, self-collected sample” if the patient collected the sample (blood or oral fluid) and sent it to the laboratory for testing.

#### 9.2.1 HIV-1/2 RNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest nucleic acid amplification test (NAAT). (**Required**, applies to health department & health care providers)

#### 9.2.2 HIV-1 RNA NAAT (QUALITATIVE and QUANTITATIVE)

- Enter the collection date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the qualitative result of the test. (**Required**, applies to health department & health care providers)
- For all reactive qualitative results, record the result for the analyte (quantitative result). (**Required**, applies to health department & health care providers)
  - Where results are reported as “Detected” above the limit of quantification (LOQ), select “Detectable above limit” and the result value in the copies/mL field. For example, a result of “>10,000,000 cp/mL detected” should be entered into the copies/ml field as “greater than detectable by this assay - 10,000,000 cp/mL”.
  - Where results are reported as “Detected”, select “Detectable within limits” and the result value in the copies/mL field.
  - Where the results reported as “Detected” below the LOQ, select “Detectable below limit” and the result value in the copies/mL field. For example, a result of “<20 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 20 cp/mL”.

#### 9.2.3 HIV-1 RNA/DNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest NAAT. (**Required**, applies to health department & health care providers)

#### 9.2.4 HIV-1 Culture

- Enter result and collection date of earliest culture result. (**Required**, applies to health department & health care providers)

#### 9.2.5 HIV-2 RNA/DNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest NAAT. (**Required**, applies to health

department & health care providers)

#### 9.2.6 HIV-2 Culture

- Enter result and collection date of earliest culture result. (**Required**, applies to health department & health care providers)

#### 9.2.7 HIV-1 RNA/DNA NAAT (QUANTITATIVE)

- Enter date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the result of the test. (**Required**, applies to health department & health care providers)
  - Where results are reported as “Detected” above the limit of quantification (LOQ), select “Detectable above limit” and the result value in the copies/mL field. For example, a result of “>10,000,000 cp/mL detected” should be entered into the copies/ml field as “greater than detectable by this assay - 10,000,000 cp/mL”.
  - Where results are reported as “Detected”, select “Detectable within limits” and the result value in the copies/mL field.
  - Where the results reported as “Detected” below the LOQ, select “Detectable below limit” and the result value in the copies/mL field. For example, a result of “<20 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 20 cp/mL”.
  - Where the results reported as “Not detected”, select “Not detected”.

#### 9.2.8 HIV-2 RNA/DNA NAAT (QUANTITATIVE)

- Enter date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the result of the test. (**Required**, applies to health department & health care providers)
  - Where results are reported as “Detected” above the limit of quantification (LOQ), select “Detectable above limit” and the result value in the copies/mL field. For example, a result of “>10,000,000 cp/mL detected” should be entered into the copies/ml field as “greater than detectable by this assay - 10,000,000 cp/mL”.
  - Where results are reported as “Detected”, select “Detectable within limits” and the result value in the copies/mL field.
  - Where the results reported as “Detected” below the LOQ, select “Detectable below limit” and the result value in the copies/mL field. For example, a result of “<20 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 20 cp/mL”.
  - Where the results reported as “Not detected”, select “Not detected”.

### 9.3 DRUG RESISTANCE TESTS (GENOTYPIC)

- This section should be completed if there is evidence of a drug resistance test (genotypic), regardless of the type of drug resistance test, in the patient’s medical or other record.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter the collection date of the earliest test. (**Required**, applies to health department & health care providers)
- When entering this information in eHARS, you should use the “Lab Data” tab and choose “HIV-1 Genotype (Unspecified)” as the test type. You will not be able to enter a genotype sequence since this test type only captures evidence of a drug resistance test (genotypic). If a corresponding genotype sequence is subsequently received, you should import this



information as a separate laboratory document using the test type that reflects the type of drug resistance test that was conducted (e.g., HIV-1 Genotype (PR/RT RNA Nucleotide Sequence-Sanger method)).

#### 9.4 IMMUNOLOGIC TESTS (CD4 COUNT AND PERCENTAGE)

- Enter the results of *all* HIV-related CD4 tests that are available from the source where information is being collected to complete the form. At minimum, the first CD4 results closest to the date of initial HIV infection diagnosis should be reported and the first CD4 results indicative of stage 3 (AIDS) should be reported if available.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Whenever CD4 count and percentage are both available for the same specimen collection date, record both.
- Enter specimen collection date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011). (**Required**, applies to health department & health care providers)

##### 9.4.1 CD4 COUNT

- Enter result and specimen collection date of all CD4 counts. (**Required**, applies to health department & health care providers)

##### 9.4.2 CD4 PERCENTAGE

- Record result and specimen collection date of all CD4 percentages. (**Required**, applies to health department & health care providers)

#### 9.5 DOCUMENTATION OF TESTS

##### 9.5.1 DID DOCUMENTED LABORATORY TEST RESULTS MEET APPROVED HIV DIAGNOSTIC ALGORITHM CRITERIA? (**Required** if applicable, applies to health department & health care providers)

- This section captures diagnoses through novel algorithms and should only be completed if none of the following were positive for **HIV-1**: western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen test, or nucleotide sequence.
- HIV-1 antigen analyte results from combination antigen/antibody tests in which the antigen result can be differentiated from the antibody result, such as an “HIV-1/2 Ag/Ab differentiating immunoassay” or an “HIV-1/2 Ag/Ab and type-differentiating immunoassay”, are *not* considered stand-alone p24 antigen tests. Refer to sections 9.1.5 and 9.1.6 for more information regarding combination Ag/Ab IA.
- “Yes” indicates that the test results were determined to be part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2 (refer to the most recent case definition for HIV infection available at <https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/>), regardless of whether the tests were approved for other purposes such as laboratory-based HIV testing or point-of-care HIV screening.
  - If “Yes”, enter date of earliest positive test result for this algorithm in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011). (**Required** if applicable, applies to health department & health care providers).
- “No” indicates that the test results were determined to *not* be a part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2.



- “Unknown” indicates that you are unable to determine whether the test results were part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2.
- Values of “No” and “Unknown” should generally not be selected. This form is intended to be used to ascertain that two tests *are* part of an algorithm that meet the HIV surveillance case definition. Carefully review all “No” and “Unknown” responses before entering into the surveillance system.

9.5.2 IS EARLIEST EVIDENCE OF HIV INFECTION DIAGNOSIS DOCUMENTED BY A PHYSICIAN RATHER THAN BY LABORATORY TEST RESULTS? (**Required** if applicable, applies to health department & health care providers)

- If laboratory evidence of an HIV test is unavailable or was insufficient to meet surveillance case definition in the patient’s medical or other record and written documentation of laboratory evidence of HIV infection consistent with the HIV case definition is noted by the physician, enter “Yes”; otherwise enter “No” or “Unknown”.
- IF “YES” TO 9.5.2, PROVIDE DATE OF DIAGNOSIS BY PHYSICIAN (**Required** in the absence of laboratory results, applies to health department & health care providers)
- Date of diagnosis is defined as the date (at least the year) of diagnosis reported in the content of the medical record. If the diagnosis date was not reported in the note, the date when the note was written can be used as a proxy. For example, if a health care provider writes a note in a medical chart on 4/10/2010 stating the patient had received a diagnosis of HIV infection on 2/11/2010, then 2/11/2010 should be recorded as the date of diagnosis by the physician.

9.5.3 DATE OF LAST DOCUMENTED NEGATIVE HIV TEST RESULT (SPECIFY TYPE) (**Required**, applies to health department & health care providers)

- This represents the last documented date when the patient was considered not to be HIV infected, as documented by laboratory or medical record evidence accompanied by test type information.
- Patient self-report of last negative test result is not considered “documented” and thus should not be entered in this field but rather in the HIV Testing History section (see sections 12.6 and 12.7 below).
- Enter the specimen collection date for the date of the last negative HIV test result in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03././2011). (**Required**, applies to health department & health care providers)
- Enter the type of test that yielded the last negative HIV test result. (**Required**, applies to health department & health care providers)
- Include the last negative HIV laboratory test result before the patient was known to be infected. Do not include in this field a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV. Negative test results that are part of a sequence of HIV tests in an algorithm should be recorded in the appropriate laboratory test fields above.
- If it is unclear how to interpret a negative test result that is part of a testing algorithm, it may be necessary to contact the provider ordering the tests.
- Do not include an undetectable viral load result, unless there is evidence that the patient was **not** receiving antiretroviral therapy at the time the viral load specimen was obtained. A viral load result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained, or may naturally have a suppressed viral load without antiretroviral therapy).

- Do not include tests with indeterminate, inconclusive, or unknown results in this field. Any indeterminate HIV test results that are part of a diagnostic testing algorithm should be recorded in the appropriate laboratory test fields above.

## 10. Treatment/Services Referrals

### X. Treatment/Services Referrals (record all dates as mm/dd/yyyy)

Has this patient been informed of his/her HIV infection? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		This patient's partners will be notified about their HIV exposure and counseled by <input type="checkbox"/> 1-Health dept <input type="checkbox"/> 2-Physician/Provider <input type="checkbox"/> 3-Patient <input type="checkbox"/> 9-Unknown	
Evidence of receipt of HIV medical care other than laboratory test result (select one; record additional evidence in Comments) <input type="checkbox"/> 1-Yes, documented <input type="checkbox"/> 2-Yes, client self-report, only Date of medical visit or prescription ____/____/____			
<b>For Female Patient</b>			
This patient is receiving or has been referred for gynecological or obstetrical services <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Is this patient currently pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Has this patient delivered live-born infants? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>For Children of Patient</b> (record most recent birth in these boxes; record additional or multiple births in Comments)			
*Child's Name		Child's Date of Birth ____/____/____	
Child's Last Name Soundex		Child's State Number	
Facility Name of Birth (if child was born at home, enter "home birth")		*Phone ( )	
<b>Facility Type</b> <u>Inpatient:</u> <u>Outpatient:</u> <u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Other, specify _____			
*Street Address		*ZIP Code	
City	County	State/Country	

- Treatment/services referrals information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.

- 10.1 HAS THIS PATIENT BEEN INFORMED OF HIS/HER HIV INFECTION (**Optional**, applies to health department & health care providers)
  - Select applicable response
  - If notification is not documented, select "Unknown" unless the person completing the form knows with certainty that the patient is aware of the infection.
- 10.2 THIS PATIENT'S PARTNERS WILL BE NOTIFIED ABOUT THEIR HIV EXPOSURE AND COUNSELED BY (**Optional**, applies to health department & health care providers)
  - Select applicable response.
- 10.3 EVIDENCE OF RECEIPT OF HIV MEDICAL CARE OTHER THAN LABORATORY TEST RESULT (**Optional**, applies to health department & health care providers)
  - Select applicable response.
  - Additional evidence may be recorded in the Comments section. In eHARS, enter on the "Comments" tab.
- 10.4 DATE OF MEDICAL VISIT OR PRESCRIPTION
  - Enter date in *mm/dd/yyyy* format. If day is unknown, use ".." for the unknown value (e.g., 03../2017).
- 10.5 FOR FEMALE PATIENT
  - Complete if the patient's sex assigned at birth is female.
- 10.5.1 THIS PATIENT IS RECEIVING OR HAS BEEN REFERRED FOR GYNECOLOGICAL OR OBSTETRICAL SERVICES (**Optional**, applies to health department & health care providers)
  - Select applicable response.
- 10.5.2 IS THIS PATIENT CURRENTLY PREGNANT (**Required**, applies to health department & health care providers)
  - Response is dependent on which date was selected for populating the field 3.9 (DATE

FORM COMPLETED). If patient was pregnant on that date, select “Yes”.

- 10.5.3 HAS THIS PATIENT DELIVERED LIVE-BORN INFANTS (**Optional**, applies to health department & health care providers)
- Select applicable response.
  - If “Yes”, provide birth information for the most recent birth as described at 10.6 below.

10.6 FOR CHILDREN OF PATIENT

- Record information related to the most recent birth in this section. Record additional or multiple births in the Comments section. In eHARS, enter the additional births on the “Treatment” tab.
- 10.6.1 CHILD’S NAME (**Recommended**, applies to health department & health care providers)
- Enter child’s first name, middle name, and last name.
- 10.6.2 CHILD’S DATE OF BIRTH (**Recommended**, applies to health department & health care providers)
- Enter child’s date of birth in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
- 10.6.3 CHILD’S LAST NAME SOUNDEX (**System generated**)
- After the child’s name is entered into eHARS, the software automatically generates this variable by using the child’s last name. After the code is generated, health department staff should fill this field on the form.
  - This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created.
- 10.6.4 CHILD’S STATE NUMBER (**Recommended**, applies to health department)
- Enter the assigned state number, if applicable. This number is typically assigned by state/local health department personnel if the child is known to have received a diagnosis of HIV infection. Some jurisdictions also assign numbers for children classified as “Perinatally HIV Exposed” or “Seroreverter”.
  - If a child was a pediatric “Seroreverter” and was later infected with HIV, the child must be given two different state numbers, one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to Appendix 4.1.4 in the Technical Guidance File *Pediatric HIV Confidential Case Report Form* for the definition of a pediatric “Seroreverter”. Enter the child’s state number associated with the “Seroreverter” on the case report form.
  - Assigned numbers **must not** be reused, even if the case is later deleted.
  - This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge the state datasets without duplication.
- 10.6.5 FACILITY NAME OF BIRTH (**Optional**, applies to health department & health care providers)
- Enter the name of the facility where the child was born.
  - If the child was born at home, enter “home birth”.
- 10.6.6 PHONE (**Optional**, applies to health department & health care providers)
- Enter area code and telephone number of the facility of birth.
- 10.6.7 FACILITY TYPE (**Optional**, applies to health department & health care providers)
- Select the type of facility of birth.

- Refer to the *eHARS Technical Reference Guide* for listing of facility types.
- 10.6.8 STREET ADDRESS (**Optional**, applies to health department & health care providers)
  - Enter street address of the facility of birth.
- 10.6.9 ZIP CODE (**Optional**, applies to health department & health care providers)
  - Enter ZIP code where the facility of birth is located.
- 10.6.10 CITY (**Optional**, applies to health department & health care providers)
  - Enter city of the facility of birth.
- 10.6.11 COUNTY (**Optional**, applies to health department & health care providers)
  - Enter county of the facility of birth.
- 10.6.12 STATE/COUNTRY (**Optional**, applies to health department & health care providers)
  - Enter state and country name of the facility of birth.

## 11. Antiretroviral Use History

### XI. Antiretroviral Use History (record all dates as mm/dd/yyyy)

Main source of antiretroviral (ARV) use information (select one)			Date patient reported information	
<input type="checkbox"/> Patient interview <input type="checkbox"/> Medical record review <input type="checkbox"/> Provider report <input type="checkbox"/> NHM&E <input type="checkbox"/> Other			____/____/____	
Ever taken any ARVs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown				
If yes, reason for ARV use (select all that apply)				
<input type="checkbox"/> HIV Tx	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____	
<input type="checkbox"/> PrEP	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____	
<input type="checkbox"/> PEP	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____	
<input type="checkbox"/> PMTCT	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____	
<input type="checkbox"/> HBV Tx	ARV medications _____	Date began ____/____/____	Date of last use ____/____/____	
<input type="checkbox"/> Other (specify reason) _____		Date began ____/____/____	Date of last use ____/____/____	

- ARV use history data are used to assess the prevalence of acquired and transmitted HIV drug resistance.
  - Unlike other sections on the ACRF, patient self-reported information is accepted for all answers.
- 11.1 MAIN SOURCE OF ANTIRETROVIRAL (ARV) USE INFORMATION (**Required**, applies to health department & health care providers)
- Check only one source (the main source from which the information in this section was obtained).
    - “*Patient Interview*” should be selected only if the patient was directly asked a series of questions from this or another structured form. Interviewer should have been trained on the proper collection of ARV use history data.
    - “*Medical Record Review*” indicates that this information was obtained through abstraction of medical charts, electronic medical records or databases.
    - “*Provider Report*” indicates this form was filled out by a health care provider.
    - “*NHM&E*” indicates that data were abstracted from the National HIV Monitoring and Evaluation (NHM&E) project forms or databases.
    - “*Other*” indicates that information came from a source other than those listed above.
- 11.2 DATE PATIENT REPORTED INFORMATION (**Required**, applies to health department & health care providers)
- The appropriate date to enter depends on the MAIN SOURCE OF ARV USE INFORMATION. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
  - If there was a structured patient interview, enter the date of interview.
  - For a medical record review, enter the date of the most recent patient encounter that contributed to the ARV information collected. If there was no patient encounter, then enter

the date the medical record was reviewed. If the ACRF was completed by a health care provider, enter the date of the most recent patient encounter during which the ARV information was obtained from the patient. If the provider information was obtained from another data source, enter the date of receipt of the information. If these dates are not available, enter the date the ACRF was completed.

- For information obtained through NHM&E, use the date entered on the HIV testing form.
- If there are no data available from the above sources, enter the date the ACRF was completed.

11.3 EVER TAKEN ANY ARVS (**Required**, applies to health department & health care providers)

- This variable indicates whether the patient has ever taken any antiretroviral medication. “Yes” indicates there is evidence that the patient has taken ARVs, including self-report.
- If “Yes”, it is important to enter the dates when use began and, if appropriate, ended. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- “No” indicates there is evidence that the patient has never taken ARVs.
- “Unknown” should be used when the person completing the form does not know whether or not the patient has ever taken ARVs, after searching for the information or asking the patient.
- Leave the field blank if there was no attempt to find the information.

11.4 IF YES, REASON FOR ARV USE (**Required**, applies to health department & health care providers)

- Select all that apply.
- “HIV Tx” indicates that the patient used ARVs to treat HIV infection.
- “PrEP” indicates that the patient used ARVs prior to HIV diagnosis for HIV preexposure prophylaxis (PrEP). If “PrEP” is selected, please refer to the updated clinical practice guideline for PrEP at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. For surveillance activities, additional follow up with health care providers may be required for certain test results for final determination of HIV status.
- “PEP” indicates that the patient used ARVs as postexposure prophylaxis (PEP).
- “PMTCT” indicates that the patient used ARVs to prevent HIV mother-to-child-transmission during pregnancy.
- “HBV Tx” indicates that the patient used ARVs to treat hepatitis B virus infection.
- “Other” indicates that the patients used ARVs for a reason other than those indicated above.

11.5 ARV MEDICATIONS (**Recommended**, applies to health department & health care providers)

- For each ARV use reason indicated in 11.4, list the medications taken.
- This variable is used to verify that the medication taken was actually an antiretroviral.
- It is not necessary to list every drug combination that may have been used; record at least one ARV. Enter “unspecified” if an ARV was taken but the name is not known.

11.6 DATE BEGAN (**Required**, applies to health department & health care providers)

- For each ARV use reason indicated in 11.4, enter the earliest date that the patient took the ARVs, even if ARV use was sporadic.
- If the first time ARVs were taken occurred after HIV diagnosis, it is very important to enter a date, even an estimated date, later than the date of HIV diagnosis.
- Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).

11.7 DATE OF LAST USE (**Required**, applies to health department & health care providers)

- For each ARV use reason indicated in 11.4, enter the most recent date of ARV use.
- For patients currently on ARVs, record the date of the most recent prescription or known usage. If the information was collected during a patient interview, the date would be the interview date. If the information was collected as part of a medical record review, record the

- date of the most recent prescription or date of the most recent physician's note.
- Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).

## 12. HIV Testing History

### XII. HIV Testing History (record all dates as mm/dd/yyyy)

Main source of testing history information (select one)		Date patient reported information
<input type="checkbox"/> Patient interview <input type="checkbox"/> Medical record review <input type="checkbox"/> Provider report <input type="checkbox"/> NHM&E <input type="checkbox"/> Other		___/___/___
Ever had previous positive HIV test result? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Date of first positive HIV test result ___/___/___
Was the first positive test result from a self-test performed by the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
Ever had a negative HIV test result? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Date of last negative HIV test result (if date is from a lab test with test type, enter in Lab Data section) ___/___/___
Was the last negative test result from a self-test performed by the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
Number of negative HIV test results within the 24 months before the first positive test result ___		<input type="checkbox"/> Unknown
How many of these negative test results were from self-tests performed by the patient? ___		<input type="checkbox"/> Unknown

- Unlike other sections on the ACRF, patient self-reported information is accepted for all answers.

#### 12.1 MAIN SOURCE OF TESTING HISTORY INFORMATION (**Required**, applies to health department & health care providers)

- Check only one source (the main source from which the information in this section was obtained).
  - “*Patient Interview*” should be selected only if the patient was directly asked a series of questions from this or another structured form. Interviewer should have been trained on the proper collection of testing history data.
  - “*Medical Record Review*” indicates that this information was obtained through abstraction of medical charts, electronic medical records, or databases. Information may also have come from a database of HIV test results or pharmacy records.
  - “*Provider Report*” indicates this form was filled out by a health care provider.
  - “*NHM&E*” indicates that data were abstracted from the National HIV Monitoring and Evaluation (NHM&E) project forms or databases.
  - “*Other*” indicates that information came from a source other than those listed above.

#### 12.2 DATE PATIENT REPORTED INFORMATION (**Required**, applies to health department & health care providers)

- The appropriate date to enter depends on the MAIN SOURCE OF TESTING HISTORY INFORMATION. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
- For a medical record review, enter the date of the last patient encounter that contributed to the testing history information collected. If only a laboratory report was accessed, enter the date of receipt of the laboratory results. If there was no patient encounter or laboratory test receipt date, then enter the date the medical record review was performed.
- If there was a structured patient interview, enter the date of the interview.
- If the ACRF was completed by a health care provider, enter the date of the last patient encounter when the most recent testing history information was obtained from the patient. If provider's information only came from another data source, such as a laboratory report, enter the date of receipt of the information. If there are no such dates, enter the date the ACRF was completed.
- For information obtained through NHM&E, use the date entered on the HIV Test Form.
- If there are no data available from the above sources, enter the date the ACRF was completed.

#### 12.3 EVER HAD PREVIOUS POSITIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)



- The purpose of this variable is to ascertain whether a positive HIV test result occurred earlier than the current HIV diagnosis date but was not reported to the HIV surveillance system. For example, a patient could have been diagnosed in another state/country or tested anonymously.
  - Self-reported information is acceptable.
  - “Yes” indicates sufficient evidence that there was a previous positive HIV test result.
  - “No” indicates sufficient evidence that there was no previous positive HIV test result.
  - “Unknown” indicates that there is lack of evidence about previous HIV test results. Select “Unknown” if the patient refused to answer the question, if the facility refused to permit medical record review, or if the patient, chart reviewer, or provider had no knowledge of whether or not there was a previous positive HIV test result after searching for the information or asking the patient.
  - The field should be left blank if the medical record was not searched or the question was not asked.
  - Do not include indeterminate HIV test results, false positive test results, and tests with inconclusive or unknown results.
- 12.4 DATE OF FIRST POSITIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)
- “Yes” indicates that there was a known previous positive HIV test result. Record the date of the earliest known positive HIV test result, including patient self-reported dates and anonymous tests. It is acceptable to enter an estimated or incomplete date, as long as it contains a year. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
  - “No” indicates there were no known previous positive HIV test results. Enter the date of the current positive HIV test result (i.e., the collection date of the current diagnostic HIV test).
  - If you do not know the date of HIV diagnosis, enter the earliest known positive HIV test result.
  - Do not include indeterminate HIV test results, false positive test results, and tests with inconclusive or unknown results.
- 12.5 WAS THE FIRST POSITIVE TEST RESULT FROM A SELF-TEST PERFORMED BY THE PATIENT (**Required**, applies to health department & health care providers)
- “Yes” indicates that first positive test was a self-test performed by the patient.
  - “No” indicates the first positive test result was not a self-test performed by the patient.
- 12.6 EVER HAD A NEGATIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)
- This variable ascertains whether or not the patient ever had a negative HIV test result at any time in the past that indicated the patient was not HIV infected. The mere absence of information about previous tests in a medical record should not be recorded as “No”, since tests can occur in other venues. Do not include a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV.
  - Self-reported information is acceptable for this data field.
  - “Yes” indicates there is knowledge of a previous negative HIV test result, either self-reported or confirmed by a laboratory report.
  - “No” indicates there is evidence that the patient never had a negative HIV test result (e.g., patient states they have never been tested before). Do not enter “No” if there is simply no evidence either way about a previous HIV test result.

- “Unknown” indicates there is insufficient evidence supporting or denying the occurrence of a negative HIV test result, after searching for the information or asking the patient. Leave the field blank if there was no attempt to find the information.
  - Do not include an undetectable viral load result, as this result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained or may naturally have a suppressed viral load without antiretroviral therapy).
  - Do not include tests with indeterminate, inconclusive, or unknown results.
- 12.7 DATE OF LAST NEGATIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)
- This variable represents the last date when the patient was considered not to be HIV infected, based on self-reported information, or by physician or testing site reports that do not have documented laboratory test result and type information.
  - Negative HIV test result dates documented by a laboratory report or medical record accompanied by test type information should be entered in the Laboratory Data section (9.6.3) and not here. Incomplete dates are acceptable if the year is included. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
  - Do not include a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV.
  - Do not include an undetectable viral load result, as this result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained or may naturally have a suppressed viral load without antiretroviral therapy).
  - Do not include tests with indeterminate, inconclusive, or unknown results.
- 12.8 WAS THE LAST NEGATIVE TEST RESULT FROM A SELF-TEST PERFORMED BY THE PATIENT (**Required**, applies to health department & health care providers)
- “Yes” indicates that first positive test was a self-test performed by the patient.
  - “No” indicates the first positive test result was not a self-test performed by the patient.
- 12.9 NUMBER OF NEGATIVE HIV TEST RESULTS WITHIN 24 MONTHS BEFORE FIRST POSITIVE TEST RESULT (**Required**, applies to health department & health care providers)
- Count the number of negative HIV test results in the 24 months before the first positive HIV test.
  - Enter “0” if it is known that the patient has never been tested for HIV before or never had a negative test result. Do not enter “0” if there is simply no evidence about a previous HIV test result.
  - “Unknown” indicates there is evidence that the patient refused to answer the question, the facility refused to permit medical record review, the patient does not remember whether they had a negative test result, or the provider or abstractor has no evidence about whether or not there was a previous test result. Leave the field blank if there was no attempt to find the information.
  - Do not include a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV.
  - Do not include an undetectable viral load result, as this result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained or may naturally have a suppressed viral load without antiretroviral therapy).
  - Do not include tests with indeterminate, inconclusive, or unknown results.
- 12.10 HOW MANY OF THESE NEGATIVE TEST RESULTS WERE FROM SELF-TESTS



PERFORMED BY THE PATIENT? (**Required**, applies to health department & health care providers)

- Of the total number of negative HIV test results within 24 months before first positive test result from 12.9, enter the number of tests that were self-tests performed by the patient.
- Enter “0” if it is known that the patient has never had a self-test with a negative test result. Do not enter “0” if there is simply no evidence about a previous self-test with a negative test result.
- “Unknown” indicates there is evidence that the patient refused to answer the question, the facility refused to permit medical record review, the patient does not remember whether they had a negative test result, or the provider or abstractor has no evidence about whether or not there was a previous test result. Leave the field blank if there was no attempt to find the information.

### 13. Comments (Optional, applies to health department & health care providers)

#### **XIII. Comments**


- This section can be used for information not requested on the form or for information requested but where there might not be room in the space provided.
- As appropriate, information collected in this section can be entered in existing fields on the ACRF of eHARS.
- Information entered into the “Comments” tab on the ACRF of eHARS will not be transmitted to CDC.

### 14. Local/Optional Fields (Optional, applies to health department)

#### **XIV. \*Local/Optional Fields**


- This section is for collection of data that are not on the form at the state and local level.
- This information is not sent to CDC.

# Appendix: Adult HIV Confidential Case Report (CDC 50.42A)

## Instructions for Completion

### 5. Residence at Diagnosis

- Residence may be identical to that listed above in Patient Identification, unless otherwise noted in the chart.
- For HIV, stage 0, 1, 2, and unknown case reports, enter residence at the date of HIV infection diagnosis. The date of diagnosis of HIV infection is the earliest date on which the surveillance case definition for HIV infection, any stage, was satisfied in accordance with laboratory and clinical criteria (see the Revised Surveillance Case Definition for HIV Infection at <http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf>).
- If a test result is not available, enter patient's residence at the date of *physician diagnosis* of HIV infection.
- For HIV, stage 3 (AIDS) case reports, enter patient's residence at the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.

Residence assignment can be problematic for patients who:

- Have multiple residences
- Are on vacation
- Reside at a school
- Are foster children
- Are members of the armed forces
- Are institutionalized in correctional or other types of facilities
- Are foreign to the United States
- Are US citizens diagnosed abroad
- For further guidance about residency assignment, see Technical Guidance File *Date and Place of Residence*.

### 6. Facility of Diagnosis

#### 6.2 FACILITY NAME

- For HIV, stage 0, 1, 2, and unknown case reports, enter the name of the facility associated with the date of HIV infection diagnosis. The date of diagnosis of HIV infection is the earliest date on which the surveillance case definition for HIV infection, any stage, was satisfied in accordance with laboratory and clinical criteria (see the Revised Surveillance Case Definition for HIV Infection at <http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf>).
- If test results are not in the medical record, enter the name of the facility where the patient's HIV infection was diagnosed and documented by the health care provider.
- For HIV, stage 3 (AIDS) case reports, enter the name of the facility associated with the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.
- Enter facility uniformly to prevent the occurrence of multiple names for a given facility.

### 7. Patient History

- This information is often found in a discharge summary, history and physical, social service notes, HIV testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact patient's provider about risk factor information.

- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection.
- This information can be difficult to find, particularly if the patient has not been interviewed. States should have risk factor ascertainment procedures tailored to their jurisdictions.

## 8. Clinical: Acute HIV Infection and Opportunistic Illnesses

### 8.1. CLINICAL: ACUTE HIV INFECTION

#### 8.1.2 CLINICAL SIGNS/SYMPTOMS CONSISTENT WITH ACUTE RETROVIRAL SYNDROME

- Acute HIV infection may be suspected in persons with signs and symptoms of acute retroviral syndrome (ARS) at or just before diagnosis and within 6 weeks after a possible exposure to HIV. Signs and symptoms of acute HIV infection may include but are not limited to one or more of the following from the list below; typically, ARS may be suspected if fever and one or more signs/symptoms are present, or in the absence of fever, two or more signs/symptoms, and differential diagnosis rules out other illness such as Epstein-Barr virus (EBV) and non-EBV infectious mononucleosis syndromes, influenza, viral hepatitis, streptococcal infection, or syphilis (Reference: Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/guidelines-adult-adolescent-arv.pdf>). However, ARS may also be clinically determined in atypical circumstances by a single sign or symptom, and include other signs or symptoms not listed below, such as opportunistic illness or unusual clinical manifestations. (Reference: Braun DL, Kouyou RD, Blamer B, Grube C, Weber R, Gunthard HF. Frequency and spectrum of unexpected clinical manifestations of primary HIV-1 infection. CID 2015; 61:1013-1021).
- Signs/symptoms:
  - Clinical manifestation
    - Fever
    - Malaise/fatigue
    - Pharyngitis
    - Rash
    - Lymphadenopathy
    - Weight loss
    - Headache
    - Diarrhea
    - Night sweats
    - Myalgia
    - Nausea
    - Arthralgia
    - Cough
    - Vomiting
    - Oral ulcers
    - Neurological symptoms
    - Genital ulcers
  - Elevated liver enzymes
  - Thrombocytopenia

## **National HIV Surveillance System (NHSS)**

### **Attachment 4(b)**

Technical Guidance for HIV Surveillance Programs:  
Pediatric HIV Confidential Case Report Form

# Technical Guidance for HIV Surveillance Programs

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## **Pediatric HIV Confidential Case Report Form**

HIV Surveillance Branch  
Atlanta, Georgia

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# Instructions for Completion

## Purpose of Case Report Form

The Pediatric HIV Confidential Case Report (CDC 50.42B) form (PCRf) is designed to collect information that promotes understanding of perinatal HIV exposure and HIV infection morbidity and mortality among patients less than 13 years of age at time of diagnosis. This form reflects data that is required to be collected and some that is recommended or optional. This guidance applies to all perinatal HIV exposure and HIV infection data collection even if state or local surveillance programs use a different form or medium for perinatal HIV exposure and HIV case surveillance. See [Appendix](#) for further guidance.

Prior to 2023, CDC provided a separate *Perinatal HIV Exposure Reporting* (PHER) form to facilitate collection of additional standardized data on HIV-exposed children. CDC revised the PCRf to include some additional standardized data on HIV-exposed children and retired the separate PHER form in 2023.

## The Case Report Form in the Context of Document-Based Surveillance

Unlike case-based data management, document-based data management allows all documents to be stored and retained electronically in their original formats. Instead of completing one form for a reported case, fill out the applicable part of the form for each data source contributing information to that perinatal HIV exposure or HIV case.

Accurate data abstraction is critical. For example, the dates of receipt of prenatal care should be before the infant's date of birth. If inconsistent information is found in medical records indicate that in the Comments section on the data abstraction form. This will serve as documentation that the inconsistency was in the medical record and is not an error in abstraction, notation, or data entry. The HIV Surveillance Coordinator in each jurisdiction, or their designee, should review all forms before the data are entered.

## Patients for Whom Form is Indicated

- Each child less than 13 years of age, who meets the HIV infection or stage 3 (AIDS) case definition (available at <https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/>).
- For perinatal exposure HIV reporting, all children born to HIV-infected persons. This includes only live births. The definition of a live birth as defined by the World Health Organization is: '...the complete expulsion or extraction from its [birthing person] of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born.' Thus, if a birth certificate has been completed for the infant and birthing person was HIV-infected, the form should be completed.
- Includes each child whose infection status has not yet been determined, seroconverters, and those exposed but determined not to be infected with HIV; inclusion of such patients is for public health surveillance purposes only.
- Each child with HIV infection progressing from an earlier or unknown stage to stage 3 (AIDS) diagnosis before 13 years of age.
- Each child with HIV infection who has been reported but for whom updated information is available such as new CD4 tests, viral load tests, or drug resistance tests (genotypic) reported from a medical provider, additional risk factor information, updated current address information, or a change in vital status.
- For each follow-up (typically every 6 months) of a child with perinatal HIV exposure whose

infection status has not been determined until the diagnostic status is known or up to 18 months of age.

If the data is collected electronically and can be imported, recording the information on a hardcopy form is not necessary. A federal assurance of confidentiality applies to information on children exposed perinatally with or without consequent infection.

## Definition of Variable Designators

- **Required:** Variables that must be collected by all programs. Please note that for some of these variables there must be a known value reported in order to meet the eligibility criteria for data associated with the patient to be transmitted to the Centers for Disease Control and Prevention (CDC) through the CDC-supplied enhanced HIV/AIDS Reporting System (eHARS). The *eHARS Technical Reference Guide* details the specific variables required to meet the eligibility criteria at the beginning of Chapter 3. The *eHARS Technical Reference Guide* can be accessed through SharePoint: <https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>.
- **Recommended:** Variables that programs are strongly encouraged to collect but are not absolutely required.
- **Optional:** Variables that programs may or may not choose to collect.
- **System generated:** Variables where the value is generated by eHARS.

## Disposition of Form

- The completed form is for state or local health agency use and is not to be sent to CDC. The Pacific Islands are the only jurisdictions that send forms to CDC for data entry and all patient identifiers must be removed before they are sent.
- Data obtained from these forms are entered into standardized computer software provided by the Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC by encrypted electronic transfer via a secure access management service.

## 1. Patient Identification

### I. Patient Identification (record all dates as mm/dd/yyyy)

*First Name		*Middle Name		*Last Name		Last Name Soun	
Alternate Name Type (example: Birth, Call Me)				*First Name		*Middle Name	
				*Last Name			
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary				*Current Address, Street			
				Address Date ____/____/____			
*Phone ( )		City		County		State/Country	
						*ZIP Code	
*Medical Record Number				*Other ID Type		*Number	

- Patient identifier information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
  - Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.
- 1.1 FIRST NAME (**Required**, applies to health department & health care providers)
    - Enter patient's first name.
  - 1.2 MIDDLE NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's middle name.
  - 1.3 LAST NAME (**Required**, applies to health department & health care providers)
    - Enter patient's last name.
  - 1.4 LAST NAME SOUNDEX (**System generated**)



- After patient name is entered into eHARS, the software automatically generates this variable by using the patient's last name. After the code is generated, health department staff should fill this field on the form.
  - This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created.
  - You can access the *eHARS Technical Reference Guide* through SharePoint:  
<https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>
- 1.5 ALTERNATE NAME TYPE (**Optional**, applies to health department & health care providers)
    - If available, write in the alternate name type (e.g., Alias, Birth Name)
  - 1.6 ALTERNATE FIRST NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's alternate first name.
  - 1.7 ALTERNATE MIDDLE NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's alternate middle name.
  - 1.8 ALTERNATE LAST NAME (**Optional**, applies to health department & health care providers)
    - Enter patient's alternate last name.
  - 1.9 ADDRESS TYPE (**Required**, applies to health department & health care providers)
    - Select one of the address types for the patient's current address.
  - 1.10 CURRENT ADDRESS, STREET (**Required**, applies to health department & health care providers)
    - Enter the patient's current street address.
  - 1.11 ADDRESS DATE (**Required**, applies to health department & health care providers)
    - Enter the earliest date that the patient was known to be residing at the current address specified in 1.10. If the patient has resided at an address more than once (and has evidence that they resided elsewhere in between), the address date captured should be the earliest date that the patient moved to the address in the most recent instance.
    - You may enter the most recent date the patient was known to be residing at the address in the Comments section. In eHARS, enter the address with the most recent address date on a separate PCRF document on the "Identification" tab.
    - Enter date in *mm/dd/yyyy* format using "." for unknown values (e.g., 03../2011).
  - 1.12 PHONE (**Required** if patient has a telephone, applies to health department & health care providers)
    - Enter patient's primary area code and telephone number associated with the current address specified in 1.10.
  - 1.13 CITY (**Required**, applies to health department & health care providers)
    - Enter patient's current city.
  - 1.14 COUNTY (**Required**, applies to health department & health care providers)
    - Enter patient's current county.
  - 1.15 STATE/COUNTRY (**Required**, applies to health department & health care providers)
    - Enter patient's current state and country name.
  - 1.16 ZIP CODE (**Required**, applies to health department & health care providers)
    - Enter patient's current zip code.
  - 1.17 MEDICAL RECORD NUMBER (**Optional**, applies to health department & health care providers)
    - Enter medical record number of the patient if available.
    - This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.

- If the patient has more than one medical record number, enter the number of the primary record that has perinatal HIV exposure, HIV infection, or stage 3 (AIDS) documentation. Additional numbers can be noted in the Comments section annotating which facility is associated with which record number. In eHARS, enter the additional medical record numbers on the “Identification” tab.
- 1.18–1.19 OTHER ID TYPE and NUMBER (**Optional**, applies to health department & health care providers)
- Enter any additional patient identifier type (such as social security number) and the number of the other identifier. For a list of ID types, please reference the *eHARS Technical Reference Guide*.

## 2. Health Department Use Only

### II. Health Department Use Only (record all dates as mm/dd/yyyy)

Date Received at Health Department ____/____/____	eHARS Document UID	State Number
Reporting Health Dept—City/County	City/County Number	
Document Source	Surveillance Method <input type="checkbox"/> Active <input type="checkbox"/> Passive <input type="checkbox"/> Follow up <input type="checkbox"/> Reabstraction <input type="checkbox"/> Unknown	
Did this report initiate a new case investigation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Report Medium <input type="checkbox"/> 1-Field visit <input type="checkbox"/> 2-Mailed <input type="checkbox"/> 3-Faxed <input type="checkbox"/> 4-Phone <input type="checkbox"/> 5-Electronic transfer <input type="checkbox"/> 6-CD/disk	

- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.
- 2.1 DATE RECEIVED AT HEALTH DEPARTMENT (**Recommended**, applies to health department)
- Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 2.2 eHARS DOCUMENT UID (**System generated**)
- Enter UID after eHARS generates this variable.
- 2.3 STATE NUMBER (**Required**, applies to health department)
- Enter the assigned state number.
  - Each patient must have a unique state number throughout the course of HIV disease (including perinatal HIV exposure) in each state/jurisdiction where they are reported. However, if the patient was a pediatric “Seroreverter” and was later infected with HIV, the patient must be given two different state numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to [Appendix 4.1.4](#) for the definition of a pediatric “Seroreverter”. Jurisdictions must use the “Same as” field on the “Duplicate Review” tab in eHARS to link the two cases. Enter the appropriate state number associated with the events being reported on the case report form. For example, if providing information about the “Seroreverter”, enter the state number associated with the “Seroreverter”.
  - Assigned numbers **must not** be reused, even if the case is later deleted.
  - This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge state datasets without duplication.
- 2.4 REPORTING HEALTH DEPARTMENT -CITY/COUNTY (**Required**, applies to health department)
- Enter name of city and county of the health department that receives the report from providers of surveillance data.
- 2.5 CITY/COUNTY NUMBER (**Optional**, applies to health department)
- Enter the assigned city/county number.
  - Each patient must have a unique city/county number throughout the course of HIV disease (including perinatal HIV exposure) assigned by the separately funded city in which they are reported. However, if the city/county number is the primary identifier and the patient was a

pediatric “Seroreverter” and was later infected with HIV, the patient must be given two different city/county numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis. Refer to [Appendix 4.1.4](#) for the definition of a pediatric “Seroreverter”. If the city/county number is the primary identifier, the jurisdiction must use the “Same as” field on the “Duplicate Review” tab in eHARS to link the two cases. Enter the appropriate city/county number associated with the events being reported on the case report form. For example, if providing information about the “Seroreverter”, enter the city/county number associated with the “Seroreverter”.

- Assigned numbers **must not** be reused, even if the case is later deleted.
- 2.6 DOCUMENT SOURCE (**Required**, applies to health department)
- Enter the code for the document source that provided the information for this report (formerly report source).
  - To clearly identify multiple data sources for a given perinatal HIV exposure or HIV case (all stages), use a separate case report form for each source.
  - Refer to the *eHARS Technical Reference Guide* for a list of the document source codes available in eHARS.
- 2.7 SURVEILLANCE METHOD (**Required**, applies to health department)
- Enter the method the case report was ascertained.
  - For definitions of active, passive, follow up, re-abstraction see Technical Guidance File *Source Data and Completeness of Reporting*.
- 2.8 DID THIS REPORT INITIATE A NEW INVESTIGATION? (**Optional**, applies to health department)
- Enter whether this case report initiated a new investigation by the health department.
- 2.9 REPORT MEDIUM (**Optional**, applies to health department)
- Health department staff review medical records at provider facilities (i.e., field visits) or receive information over the telephone, by fax, US mail, or other method, to establish a perinatal HIV exposure or HIV case and to elicit information for HIV case report forms. The health department can also receive HIV case reports from physicians, laboratories, or other individuals or institutions through electronic transfer or CD/disks. Enter the medium in which the case report was submitted.

### 3. Facility Providing Information

#### III. Facility Providing Information (record all dates as mm/dd/yyyy)

Facility Name			*Phone (     )
*Street Address			
City	County	State/Country	*ZIP Code
Facility Type	<u>Inpatient:</u> <input type="checkbox"/> Hospital <u>Outpatient:</u> <input type="checkbox"/> Private physician's office <input type="checkbox"/> Pediatric clinic <u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Pediatric HIV clinic <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____		
Date Form Completed	*Person Completing Form		*Phone (     )

- Facility information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
  - Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.
- 3.1 FACILITY NAME (**Recommended**, applies to health department & health care providers)
- Enter name of the facility providing the information.
  - If data was reported from different facilities, enter name of each on separate forms.
- 3.2 PHONE (**Recommended**, applies to health department & health care providers)
- Enter facility's current area code and telephone number.

- 3.3 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
  - Enter facility's street address.
- 3.4 CITY (**Recommended**, applies to health department & health care providers)
  - Enter city where facility providing information is located.
- 3.5 COUNTY (**Recommended**, applies to health department & health care providers)
  - Enter county where facility providing information is located.
- 3.6 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
  - Enter state and country name where facility providing information is located.
- 3.7 ZIP CODE (**Recommended**, applies to health department & health care providers)
  - Enter ZIP code where facility providing information is located.
- 3.8 FACILITY TYPE (**Required**, applies to health department & health care providers)
  - Select the type of facility providing information.
  - Refer to the *eHARS Technical Reference Guide* for additional information regarding facility types available in eHARS.
- 3.9 DATE FORM COMPLETED (**Required**, applies to health department & health care providers)
  - Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 3.10 PERSON COMPLETING FORM (**Optional**, applies to health department & health care providers)
  - Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.
- 3.11 PHONE (**Recommended**, applies to health department & health care providers)
  - Enter the telephone number of the person completing the form.

## 4. Patient Demographics

### IV. Patient Demographics (record all dates as mm/dd/yyyy)

<b>Diagnostic Status at Report</b> <input type="checkbox"/> 3-Perinatal HIV exposure <input type="checkbox"/> 4-Pediatric HIV <input type="checkbox"/> 5-Pediatric AIDS <input type="checkbox"/> 6-Pediatric seroreverter		<b>Sex Assigned at Birth</b> <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown		<b>Country of Birth</b> <input type="checkbox"/> US <input type="checkbox"/> Other/US dependency (specify) _____	
<b>Date of Birth</b> ____/____/____			<b>Alias Date of Birth</b> ____/____/____		
<b>Vital Status</b> <input type="checkbox"/> 1-Alive <input type="checkbox"/> 2-Dead		<b>Date of Death</b> ____/____/____		<b>State of Death</b> _____	
<b>Date of Last Medical Evaluation</b> ____/____/____			<b>Date of Initial Evaluation for HIV</b> ____/____/____		
<b>Gender Identity</b> <input type="checkbox"/> Boy <input type="checkbox"/> Girl <input type="checkbox"/> Transgender boy <input type="checkbox"/> Transgender girl <input type="checkbox"/> Additional gender identity (specify) _____ <input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown					
<b>Date Identified</b> ____/____/____					
<b>Sexual Orientation</b> <input type="checkbox"/> Straight or heterosexual <input type="checkbox"/> Lesbian or gay <input type="checkbox"/> Bisexual <input type="checkbox"/> Additional sexual orientation (specify) _____ <input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown					
<b>Date Identified</b> ____/____/____					
<b>Ethnicity</b> <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino <input type="checkbox"/> Unknown				<b>Expanded Ethnicity</b> _____	
<b>Race</b> (check all that apply) <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown				<b>Expanded Race</b> _____	

- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.
- 4.1 DIAGNOSTIC STATUS AT REPORT (**Optional**, applies to health department & health care providers)
    - Use one form to capture each event regardless of the interval between diagnostic status dates, and where the same source of these data reported more than one event. Fill out suitable number of case report forms:
      - Fill out the first form completely for the first event.
      - Fill out subsequent forms partially, capturing additional or updated data absent from the first form.
    - Status depends on child's age, clinical profile, and laboratory findings. Refer to [Appendix](#)

[4.1.1–4.1.4](#) for further guidance.

- 4.1.1 PERINATAL HIV EXPOSURE
- Select “Perinatal HIV Exposure” if the patient is less than 18 months of age, was born to an HIV-infected person, and has an undetermined HIV infection status.
  - Refer to [Appendix 4.1.1](#) for further guidance.
- 4.1.2 PEDIATRIC HIV
- Select “Pediatric HIV” if the patient meets the criteria specified in the Revised Surveillance Case Definition for HIV Infection in children < 13 years of age and does not meet the current CDC pediatric HIV infection stage 3 (AIDS) case definition.
  - Refer to [Appendix 4.1.2](#) for further guidance.
- 4.1.3 PEDIATRIC AIDS
- Select “Pediatric AIDS” if patient meets the current HIV infection stage 3 case definition for children < 13 years of age.
  - Refer to [Appendix 4.1.3](#) for further guidance.
- 4.1.4 PEDIATRIC SEROREVERTER
- Select “Seroreverter” if the perinatally exposed child initially has a positive HIV test but is found NOT to be HIV-infected through criteria listed in [Appendix 4.1.4](#).
  - Of the four diagnostic status categories available on the case report form, “Pediatric Seroreverter” is synonymous with “Not Infected with HIV”.
- 4.2 SEX ASSIGNED AT BIRTH (**Required**, applies to health department & health care providers)
- Select patient’s sex assigned at birth.
  - If search for this datum was completed and sex assigned at birth could not be assigned as “Male” or “Female”, select “Unknown”.
- 4.3 COUNTRY OF BIRTH (**Recommended**, applies to health department & health care providers)
- Select applicable response.
  - For patients born in US minor outlying areas, specify the name of the US dependency from the following table:
- | US Dependencies |                |
|-----------------|----------------|
| Baker Island    | Midway Islands |
| Howland Island  | Navassa Island |
| Jarvis Island   | Palmyra Atoll  |
| Johnston Atoll  | Wake Island    |
| Kingman Reef    |                |
- For patients born in any other area outside of the US and US minor outlying areas, specify the country/US dependency name.
- 4.4 DATE OF BIRTH (**Required**, applies to health department & health care providers)
- Enter patient’s date of birth in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03/./2011).
- 4.5 ALIAS DATE OF BIRTH (**Optional**, applies to health department & health care providers)
- If available, enter the alias date of birth in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03/./2011).
- 4.6 VITAL STATUS (**Required**, applies to health department & health care providers)
- Enter vital status at time of this report.
  - For further guidance on death ascertainment, see Technical Guidance File *Death Ascertainment*.
- 4.7 DATE OF DEATH (**Required** if applicable, applies to health department & health care

- providers)
- If patient is deceased, enter date of death in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
  - For further guidance on death ascertainment, see Technical Guidance File *Death Ascertainment*.
- 4.8 STATE OF DEATH (**Required**, if applicable, applies to health department & health care providers)
- If patient is deceased, enter the state name where the death occurred. If the death occurred outside of the US, enter “Foreign Country”.
- 4.9 DATE OF LAST MEDICAL EVALUATION (**Optional**, applies to health department & health care providers)
- Enter the date of the child’s last medical evaluation in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011) regardless of reason for exam. This includes emergency room visits.
- 4.10 DATE OF INITIAL EVALUATION FOR HIV INFECTION (**Optional**, applies to health department & health care providers)
- Enter the date of initial evaluation for HIV infection in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011). This is the date when HIV infection was first considered, either clinically or through laboratory evaluation.
  - For a child whose birthing person is known to be HIV infected at the time of birth and for whom assessment of HIV is done at birth, use the date of birth. This assessment does not necessarily include an order for an HIV test, although documentation of an HIV test is often the earliest evidence that the diagnosis was considered.
  - Evidence of HIV infection in a child **must be obtained on or after the birth date**.
- 4.11 GENDER IDENTITY and DATE IDENTIFIED (**Required if not perinatal exposure or perinatal transmission**, applies to health department & health care providers)
- Enter the gender identity of the patient.
  - If the patient’s stated gender identity differs from the selections provided or the patient’s stated gender identity at a point in time includes more than one of the selections provided, select “Additional gender identity” and specify the gender identity or gender identities.
  - If documented that the patient declined to provide their gender identity, select “Declined to answer”.
  - If search for this datum was completed and gender identity could not be determined or if gender identity was documented to be unknown, select “Unknown”.
  - Refer to the lookup codes in the *eHARS Technical Reference Guide* for gender identity values available in eHARS.
  - For date identified, please enter the date the patient indicated identifying as the selected gender identity, if documented. If this date is unknown, enter the date of service (e.g., medical appointment, partner services interview) for when the information on gender identity was obtained. If that date is unknown, enter the most recent date of service. You may also enter the most recent date associated with the patient’s gender identity in the Comments section. In eHARS, enter the gender identity value associated with the most recent date on a separate PCRF document on the “Demographics” tab. Record the date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
  - If the patient’s gender identity has changed over time, record the other gender identities and associated dates identified in the Comments section. In eHARS, enter each additional value on separate PCRF documents on the “Demographics” tab.
- 4.12 SEXUAL ORIENTATION and DATE IDENTIFIED (**Required if not perinatal exposure or**



**perinatal transmission**, applies to health department & health care providers)

- Enter sexual orientation of the patient.
- If the patient's stated sexual orientation differs from the selections provided or the patient's stated sexual orientation at a point in time includes more than one of the selections provided, select "Additional sexual orientation" and specify the sexual orientation or sexual orientations.
- If documented that the patient declined to provide their sexual orientation, select "Declined to answer".
- If search for this datum was completed and sexual orientation could not be determined or if the sexual orientation was documented to be unknown, select "Unknown".
- Refer to the lookup codes in the *eHARS Technical Reference Guide* for sexual orientation values available in eHARS.
- For date identified, please enter the date the patient indicated identifying as the selected sexual orientation, if documented. If this date is unknown, enter the date of service for when the information on sexual orientation was obtained. If that date is unknown, enter the most recent date of service. You may also enter the most recent date associated with the patient's sexual orientation in the Comments section. In eHARS, enter the sexual orientation value associated with the most recent date on a separate PCRf document on the "Demographics" tab. Record it in mm/dd/yyyy format using ".." for unknown values (e.g., 03../2011).
- If the patient's sexual orientation has changed over time, record other sexual orientations and associated dates identified in the Comments section. In eHARS, enter each additional value on separate PCRf documents on the "Demographics" tab.

4.13 **ETHNICITY (Required)**, applies to health department & health care providers)

- If search for this datum was completed and ethnicity could not be determined or if ethnicity was documented to be unknown, select "Unknown".
- If no search for this datum was completed, leave this field blank.
- Regardless of the availability of data on race, collect data on ethnicity.
- As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic/Latino, Not Hispanic/Latino) for a person be collected as separate variables.
- A wide variety of ethnicities may be selected from values available in eHARS. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.

4.14 **EXPANDED ETHNICITY (Optional)** if applicable, applies to health department & health care providers)

- Enter more specific ethnicity information for greater detail such as "Hispanic or Latino - Cuban" or "Hispanic or Latino - Puerto Rican".
- Refer to the *eHARS Technical Reference Guide* for listing of expanded ethnicity.

4.15 **RACE (Required)**, applies to health department & health care providers)

- Select patient's race even if information was submitted for ethnicity.
- Select more than one race if applicable.
- If no race information is available, select "Unknown".
- As of January 2003, the US Office of Management and Budget (OMB) required that systems collect multiple races for a person (OMB Policy Directive 15 updated standards); at a minimum, collect data on the following five categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.
- Refer to the *eHARS Technical Reference Guide* for further details.

4.16 **EXPANDED RACE (Optional)**, if applicable, applies to health department & health care

providers)

- Enter more specific race information for greater detail such as “American Indian or Alaska Native.Navajo” or “White.Middle Eastern or North African”.
- Refer to the *eHARS Technical Reference Guide* for listing of expanded race.

## 5. Residence at Diagnosis

### V. Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)

Address Event Type (check all that apply to address below)		<input type="checkbox"/> Residence at HIV diagnosis	<input type="checkbox"/> Residence at stage 3 (AIDS) diagnosis	<input type="checkbox"/> Residence at perinatal exposure	<input type="checkbox"/> Residence at pediatric seroreverter	<input type="checkbox"/> Check if <u>SAME</u> as current address
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary						
*Street Address						
City	County	State/Country			*ZIP Code	

- Residence information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
  - Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.
  - Refer to [Appendix 5.0](#) for further guidance.
  - If patient’s residence at HIV diagnosis and stage 3 (AIDS) diagnosis are different, enter the address information associated with the stage 3 (AIDS) diagnosis in the Comments section. In eHARS, enter the address information associated with stage 3 (AIDS) diagnosis on the “Demographics” tab with the applicable address event type.
- 5.1 ADDRESS EVENT TYPE (**Required**, applies to health department & health care providers)
    - Select the address event type for the patient’s residence at diagnosis.
    - If the patient’s residence at HIV diagnosis and stage 3 (AIDS) diagnosis was the same, you may check both.
  - 5.2 ADDRESS TYPE (**Required**, applies to health department & health care providers)
    - Select one of the address types for the patient’s address of residence at diagnosis.
  - 5.3 STREET ADDRESS (**Required**, applies to health department & health care providers)
    - Enter street address of residence at diagnosis.
  - 5.4 CITY (**Required**, applies to health department & health care providers)
    - Enter city of residence at diagnosis.
  - 5.5 COUNTY (**Required**, applies to health department & health care providers)
    - Enter county of residence at diagnosis.
  - 5.6 STATE/COUNTRY (**Required**, applies to health department & health care providers)
    - Enter the state and country name of residence at diagnosis.
  - 5.7 ZIP CODE (**Required**, applies to health department & health care providers)
    - Enter the ZIP code of residence at diagnosis.

## 6. Facility of Diagnosis

### VI. Facility of Diagnosis (add additional facilities in Comments)

Diagnosis Type (check all that apply to facility below) <input type="checkbox"/> HIV <input type="checkbox"/> Stage 3 (AIDS) <input type="checkbox"/> Perinatal exposure <input type="checkbox"/> Check if <u>SAME</u> as facility providing information			
Facility Name			*Phone ( )
*Street Address			
City	County	State/Country	*ZIP Code
Facility Type <u>Inpatient:</u> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ <u>Outpatient:</u> <input type="checkbox"/> Private physician’s office <input type="checkbox"/> Pediatric clinic <input type="checkbox"/> Pediatric HIV clinic <input type="checkbox"/> Other, specify _____ <u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____			
*Provider Name		*Provider Phone ( )	Specialty

- Facility information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
- Enter the data below for all children reported as perinatally exposed to HIV or reported with



HIV infection.

- If the patient’s HIV diagnosis and stage 3 (AIDS) diagnosis occurred at different facilities, enter the stage 3 (AIDS) facility information in the Comments section. In eHARS, enter the facility information associated with stage 3 (AIDS) diagnosis on the “Facility” tab with the applicable diagnosis type.
- 6.1 DIAGNOSIS TYPE (**Recommended**, applies to health department & health care providers)
- Enter the diagnosis type that corresponds to the facility of diagnosis being reported.
- 6.2 FACILITY NAME (**Recommended**, applies to health department & health care providers)
- Enter name of the facility where patient was first diagnosed which corresponds with the “Diagnosis Type” reported in 6.1.
  - Refer to [Appendix 6.2](#) for further details.
- 6.3 PHONE (**Recommended**, applies to health department & health care providers)
- Enter area code and telephone number of the facility of diagnosis.
- 6.4 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
- Enter street address of the facility of diagnosis.
- 6.5 CITY (**Recommended**, applies to health department & health care providers)
- Enter city of the facility of diagnosis.
- 6.6 COUNTY (**Recommended**, applies to health department & health care providers)
- Enter county of the facility of diagnosis.
- 6.7 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
- Enter state and country name of the facility of diagnosis.
- 6.8 ZIP CODE (**Recommended**, applies to health department & health care providers)
- Enter ZIP code where the facility of diagnosis is located.
- 6.9 FACILITY TYPE (**Required** applies to health department & health care providers)
- Select the type of facility of diagnosis.
  - Refer to the *eHARS Technical Reference Guide* for listing of facility types.
- 6.10 PROVIDER NAME (**Recommended**, applies to health department & health care providers)
- Enter provider’s name where the patient was first diagnosed which corresponds with the “Diagnosis Type” reported in 6.1.
- 6.11 PROVIDER PHONE (**Recommended**, applies to health department & health care providers)
- Enter area code and telephone number for provider selected in 6.10.
- 6.12 SPECIALTY (**Optional**, applies to health department & health care providers)
- Enter provider’s specialty for provider selected in 6.10.

## 7. Patient History

### VII. Patient History (respond to all questions) (record all dates as mm/dd/yyyy)

<b>Birth person's HIV infection status</b> (select one): <input type="checkbox"/> Refused HIV testing <input type="checkbox"/> Known to be uninfected after this child's birth <input type="checkbox"/> Known HIV+ before pregnancy <input type="checkbox"/> Known HIV+ during pregnancy <input type="checkbox"/> Known HIV+ sometime before birth <input type="checkbox"/> Known HIV+ at delivery <input type="checkbox"/> Known HIV+ after child's birth <input type="checkbox"/> HIV+, time of diagnosis unknown <input type="checkbox"/> HIV status unknown	
<b>Date of birth person's first positive test result to confirm infection</b> ____/____/____	<b>Child breastfed/chestfed by birth person</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <b>Child received premasticated/pre-chewed food from birth person</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>After 1977 and before the earliest known diagnosis of HIV infection, the birth person had:</b>	
Perinatally acquired HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Injected nonprescription drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>Birth person had HETEROSEXUAL relations with any of the following:</b>	
HETEROSEXUAL contact with person who injected drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with bisexual male	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>Birth person had:</b>	
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
First date received ____/____/____ Last date received ____/____/____	
Received transplant of tissue/organs or artificial insemination	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
<b>Before the diagnosis of HIV infection, this child had:</b>	
Injected nonprescription drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received clotting factor for hemophilia/coagulation disorder	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Specify clotting factor: _____ Date received ____/____/____	
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
First date received ____/____/____ Last date received ____/____/____	
Received transplant of tissue/organs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Sexual contact with male	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Sexual contact with female	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Been breastfed/chestfed by non-birth person	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Received premasticated/pre-chewed food from non-birth person	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Other documented risk (include detail in Comments)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

- Enter all data below for children reported with HIV infection. For children reported as perinatally exposed to HIV, enter data below through 7.7.4; do not enter data under the heading “Before the diagnosis of HIV infection, this child had:”.
- These data yield information about how patients may have acquired their infection.
- Respond to each risk factor, selecting “Yes” for all factors that apply; “No” for those that do not apply (only select “No” if medical record specifically states this is not a risk factor); and “Unknown” for those for which investigation failed to yield an answer. If an investigation for a particular item was not performed, then you should leave it blank. Collect data about risk factors that occurred before the earliest known diagnosis of HIV infection. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.
- Information on the child refers to circumstances or behaviors that were thought to have exposed the child to HIV, not to treatments since the child became HIV infected. For example, if the child received a blood transfusion after the documentation of HIV infection, do not enter that information on the form.
- The state or local Cases of Public Health Importance (COPHI) coordinator should contact the CDC COPHI coordinator as soon as possible if any unusual transmission circumstances are suspected. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.

#### 7.1 BIRTHING PERSON'S HIV INFECTION STATUS (**Required**, applies to health department & health care providers)

- For the birthing person, if HIV infection was diagnosed then select from boxes 3–8 (i.e., box “Known HIV+ before pregnancy” to box “HIV+, time of diagnosis unknown”), depending on information available to determine the timing of diagnosis. Where date of the birthing person’s first positive test result to confirm HIV infection is available, select the appropriate box by comparing the date of birth of the child to the date of HIV infection diagnosis of the birthing person.
  - Refer to [Appendix 7.1](#) for further guidance.
- 7.2 DATE OF BIRTHING PERSON’S FIRST POSITIVE TEST RESULT TO CONFIRM INFECTION (**Optional**, applies to health department & health care providers)
- Where the birthing person is known to be HIV infected, enter month, day, and year of the specimen collection date of the first positive test result to confirm HIV infection in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 7.3 CHILD BREASTFED/CHESTFED BY BIRTHING PERSON (**Required**, applies to health department and health care providers)
- Select applicable response.
  - Select “Yes” if there is evidence that the patient was fed milk from the birthing person’s chest or documentation indicates that the patient was bodyfed by the birthing person.
  - When the birthing person was known to be not HIV infected at the time of child’s birth an investigation should be initiated and the state/local Cases of Public Health Importance (COPHI) coordinator should be alerted. In all other situations, investigation is not required but the CDC COPHI coordinator can be consulted if interested in further investigating breastfeeding/chestfeeding as the mode of transmission.
- 7.4 CHILD RECEIVED PREMASTICATED/PRE-CHEWED FOOD FROM BIRTHING PERSON (**Required**, applies to health department and health care providers)
- Select applicable response.
  - When the birthing person was known to be not HIV infected at the time of child’s birth an investigation should be initiated and the state/local COPHI coordinator should be alerted. In all other situations, investigation is not required, but the CDC COPHI coordinator can be consulted if interested in further investigating premastication/pre-chewing as the mode of transmission.
- 7.5 AFTER 1977 AND BEFORE THE EARLIEST KNOWN DIAGNOSIS OF HIV INFECTION, THE BIRTHING PERSON HAD:
- 7.5.1 PERINATALLY ACQUIRED HIV INFECTION (**Required**, applies to health department & health care providers)
- Select applicable response.
- 7.5.2 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)
- Select applicable response.
  - Select “Yes” if the birthing person injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the birthing person was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).
- 7.6 BIRTHING PERSON HAD HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:
- This section relates to ascertainment of risk among heterosexual sex partners of the birthing person of the case patient.
  - Heterosexual contact is defined as the birthing person having sexual contact with a partner whose sex assigned at birth is different from the patient’s sex assigned at birth.
  - Verification of sex partner’s HIV infection status is not necessary.

- 7.6.1 PERSON WHO INJECTED DRUGS (**Required**, applies to health department & health care providers)
- Select applicable response. Select “Yes” if the partner injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the partner was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).
- 7.6.2 BISEXUAL MALE (**Required**, applies to health department & health care providers)
- Select applicable response. “Yes” should be selected only if the partner’s sex assigned at birth is male and there is evidence that the partner also had sex with another person whose sex assigned at birth was male.
- 7.6.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- “Coagulation disorder” or “hemophilia” refers only to a disorder of a clotting factor, which is any of the circulating proteins named Factor I, Factor II, Factor III, etc., through Factor XII. These disorders include Hemophilia A and Von Willebrand’s disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).
  - Do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
  - If a transfusion of only platelets, other blood cells, or plasma was received by the partner, then code “No” and see question 7.6.4 below.
  - If yes, alert the state/local COPHI coordinator.
- 7.6.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Consider documenting the reason for transfusion in the Comments section. In eHARS, enter on the “Comments” tab.
  - Refers to someone with documented HIV infection who received a transfusion of blood cells (red cells, white cells, platelets) or plasma.
  - If yes, alert the state/local COPHI coordinator.
- 7.6.5 TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Consider documenting the reason for transfusion/transplant in the Comments section. In eHARS, enter on the “Comments” tab.
  - If yes, alert the state/local COPHI coordinator.
- 7.6.6 PERSON WITH DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to health department & health care providers)
- Select “Yes” only if partner is known to be HIV-positive and that partner’s risk for HIV is unknown.
- 7.7 BIRTHING PERSON HAD:
- 7.7.1-7.7.3 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR), FIRST DATE RECEIVED, and LAST DATE RECEIVED (**Required**, applies to health department & health care providers)
- ‘Blood,’ is defined as a circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets).
  - ‘Blood components’ that can be transfused, include erythrocytes, leukocytes, platelets, and plasma.
  - If “Yes”, specify the month, day, and year of the first and last transfusion before the birthing person received a diagnosis of HIV infection (stage 1,2, unknown) or stage 3 (AIDS). Enter date in mm/dd/yyyy format using “..” for unknown values

- (e.g., 03/./2011).
  - Consider documenting the reason for transfusion/transplant in the Comments section. In eHARS, enter on the “Comments” tab.
  - If the last transfusion was after March 1985, alert the state/local COPHI coordinator.
- 7.7.4 RECEIVED TRANSPLANT OF TISSUES/ORGANS OR ARTIFICIAL INSEMINATION (**Required**, applies to health department & health care providers)
  - If this is the only risk factor present and the birthing person did not have HIV infection diagnosed at the time of child’s birth, the transmission mode will be initially classified as “risk not reported/identified” pending outcome of the COPHI investigation.
  - If yes, alert the state/local COPHI coordinator.
- 7.8 BEFORE THE DIAGNOSIS OF HIV INFECTION, THIS CHILD HAD
  - Alert state/local COPHI coordinator if the child had one or more of the risk factors documented in this section.
- 7.8.1 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)
  - Select applicable response.
  - Select “Yes” if the patient injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the patient was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).
- 7.8.2-7.8.4 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER, SPECIFY CLOTTING FACTOR, and DATE RECEIVED (**Required**, applies to health department & health care providers)
  - “Coagulation disorder” or “hemophilia” refers only to a disorder of a clotting factor; factors are any of the circulating proteins named Factor I through Factor XII. These disorders include Hemophilia A and Von Willebrand’s disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).
  - This risk factor is generally documented in the history and physical section of the patient’s medical chart.
  - They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
  - If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select “No”.
  - Alert state/local COPHI coordinator if child was born after March 1998 and receipt of clotting factor is the suspected mode of HIV transmission.
  - If “Yes”, then enter the specific clotting factor and the date the clotting factor was received in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 7.8.5 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR) (**Required**, applies to health department & health care providers)
  - If child received a transfusion of blood cells (red cells, white cells, and platelets) or plasma, specify month, day, and year of first and last transfusion before the patient was infected with HIV or received a diagnosis of stage 3 (AIDS). Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
  - It is often helpful to document the reason for the transfusion in the Comments section. In eHARS, enter on the “Comments” tab.
- 7.8.6 RECEIVED TRANSPLANT OF TISSUE/ORGANS (**Required**, applies to health department & health care providers)
  - The case will be initially classified as “risk not reported/identified” pending

- outcome of the no identified risk (NIR) investigation.
- 7.8.7 SEXUAL CONTACT WITH A MALE (**Required**, applies to health department & health care providers)
- If child is known to have had sexual contact/abuse, mark the appropriate box based on the partner's sex assigned at birth. If search for this datum was completed and the partner's sex assigned at birth cannot be determined, select "Unknown".
  - If this is the only risk history, the case will be initially classified as "risk not reported/identified" pending outcome of NIR investigation.
- 7.8.8 SEXUAL CONTACT WITH A FEMALE (**Required**, applies to health department & health care providers)
- If the child is known to have had sexual contact/abuse, mark the appropriate box based on the partner's sex assigned at birth. If search for this datum was completed and the partner's sex assigned at birth cannot be determined, select "Unknown".
  - If this is the only risk history, the case will be initially classified as "risk not reported/identified" pending outcome of NIR investigation.
- 7.8.9 BEEN BREASTFED/CHESTFED BY NON-BIRTHING PERSON (**Required**, applies to health department & health care providers)
- Select applicable response.
  - Select "Yes" if there is evidence that the patient was fed milk from the chest of a non-birthing person or documentation indicates that the patient was bodyfed by a non-birthing person.
- 7.8.10 RECEIVED PREMASTICATED/PRE-CHEWED FOOD FROM NON-BIRTHING PERSON (**Required**, applies to health department & health care providers)
- Select applicable response.
- 7.8.11 OTHER DOCUMENTED RISK (**Required**, applies to health department & health care providers)
- Include detail in Comments section. In eHARS, enter on the "Comments" tab.

## 8. Clinical: Opportunistic Illnesses

### VIII. Clinical: Opportunistic Illnesses (record all dates as mm/dd/yyyy)

Diagnosis	Dx Date	Diagnosis	Dx Date	Diagnosis	Dx Date
Bacterial infection, multiple or recurrent (including Salmonella septicemia)		HIV encephalopathy		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary	
Candidiasis, bronchi, trachea, or lungs		Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis		M. tuberculosis, pulmonary <sup>1</sup>	
Candidiasis, esophageal		Histoplasmosis, disseminated or extrapulmonary		M. tuberculosis, disseminated or extrapulmonary <sup>1</sup>	
Carcinoma, invasive cervical		Isosporiasis, chronic intestinal (>1 mo. duration)		Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Coccidioidomycosis, disseminated or extrapulmonary		Kaposi's sarcoma		Pneumocystis pneumonia	
Cryptococcosis, extrapulmonary		Lymphoid interstitial pneumonia and/or pulmonary lymphoid		Pneumonia, recurrent in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, Burkitt's (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, immunoblastic (or equivalent)		Toxoplasmosis of brain, onset at >1 mo. of age	
Cytomegalovirus retinitis (with loss of vision)		Lymphoma, primary in brain		Wasting syndrome due to HIV	

<sup>1</sup>If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:

### 8.1 CLINICAL: OPPORTUNISTIC ILLNESSES

#### 8.1.1–8.1.27 (**Optional**, applies to health department & health care providers)

- Select all that apply and enter diagnosis dates. Enter date in mm/dd/yyyy format using ".." for unknown values (e.g., 03../2011).
- For additional information, refer to the most recent case definition for HIV infection (available at <https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/>).

#### 8.1.28 RVCT CASE NUMBER (**Optional**, applies to health department & health care providers)

- If this patient has a verified case of tuberculosis (TB), health department staff enter the nine-digit alphanumeric code from the TB case report or TB data management system. Providers in the private and public sectors diagnosing tuberculosis in their stage 3 (AIDS) patients may get this number from TB surveillance staff.



## 9. Laboratory Data

### IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)

<b>HIV Immunoassays</b>		
TEST <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-2 IA	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
TEST <input type="checkbox"/> HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab)	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result Overall: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive HIV-1/2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	Index Value _____	
TEST <input type="checkbox"/> HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result <sup>3</sup> Overall interpretation: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Index Value _____	Index Value _____	
Analyte results: HIV-1 Ag: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Not reportable due to high Ab level	HIV-1 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated	
HIV-2 Ab: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive <input type="checkbox"/> Reactive undifferentiated	Index Value _____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	Index Value _____	
TEST <input type="checkbox"/> HIV-1/2 type-differentiating immunoassay (supplemental) (differentiates between HIV-1 Ab and HIV-2 Ab)	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result <sup>4</sup> Overall interpretation: <input type="checkbox"/> HIV positive, untypable <input type="checkbox"/> HIV-1 positive with HIV-2 cross-reactivity <input type="checkbox"/> HIV-2 positive with HIV-1 cross-reactivity	<input type="checkbox"/> HIV negative <input type="checkbox"/> HIV indeterminate <input type="checkbox"/> HIV-1 indeterminate <input type="checkbox"/> HIV-2 indeterminate <input type="checkbox"/> HIV-1 positive <input type="checkbox"/> HIV-2 positive	
Analyte results: HIV-1 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Collection Date ____/____/____	
HIV-2 Ab: <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
TEST <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 WB	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
<b>HIV Detection Tests</b>		
TEST <input type="checkbox"/> HIV-1/2 RNA NAAT (Qualitative)	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> Both (HIV-1 and HIV-2) <input type="checkbox"/> HIV, not differentiated (HIV-1 or HIV-2) <input type="checkbox"/> Neither (negative)	Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	
TEST <input type="checkbox"/> HIV-1 RNA NAAT (Qualitative and Quantitative)	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____	Collection Date ____/____/____	
Result Qualitative: <input type="checkbox"/> Reactive <input type="checkbox"/> Nonreactive	Analyte results: HIV-1 Quantitative: <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit	
Copies/mL _____	Log _____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	TEST <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-1 culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qualitative) <input type="checkbox"/> HIV-2 culture	
Test Brand Name/Manufacturer _____	Lab Name _____	
Facility Name _____	Provider Name _____	
Result <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate	Collection Date ____/____/____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	TEST <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative) <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Quantitative)	
Test Brand Name/Manufacturer _____	Lab Name _____	
Facility Name _____	Provider Name _____	
Result <input type="checkbox"/> Detectable above limit <input type="checkbox"/> Detectable within limits <input type="checkbox"/> Detectable below limit <input type="checkbox"/> Not detected	Copies/mL _____	
Collection Date ____/____/____	Log _____	
Testing Option (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample	<b>Drug Resistance Tests (Genotypic)</b>	
TEST <input type="checkbox"/> HIV-1 Genotype (Unspecified)	Test Brand Name/Manufacturer _____	
Lab Name _____	Facility Name _____	
Provider Name _____	Collection Date ____/____/____	
<b>Immunologic Tests (CD4 count and percentage)</b>		
CD4 count _____ cells/μL	CD4 percentage _____ %	
Collection Date ____/____/____	Lab Name _____	
Test Brand Name/Manufacturer _____	Provider Name _____	
Facility Name _____		

### IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy) (cont)

<b>Documentation of Tests</b>	
Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
If YES, provide specimen collection date of earliest positive test result for this algorithm ____/____/____	
Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.	
Is earliest evidence of diagnosis documented by a physician rather than by laboratory test results?	HIV-infected <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Not HIV-infected <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Date of diagnosis by physician ____/____/____
	Date of diagnosis by physician ____/____/____

<sup>2</sup>Results not directly observed by a provider should be recorded in HIV Testing History.

<sup>3</sup>Complete the overall interpretation and the analyte results.

<sup>4</sup>Always complete the overall interpretation. Complete the analyte results when available.

- Throughout this section, "Collection Date" refers to the date when the specimen was



collected or drawn. Enter collection dates in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).

- Record all laboratory test results. Include results all diagnostic tests, viral load tests, CD4 tests, and drug resistance tests (genotypic) where possible. Where the number of test results exceeds the number of fields available on the form, record such results in the Comments section. In eHARS, enter the additional test results on the “Lab Data” tab with the applicable test type.
- Include tests with negative or indeterminate results that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). For information on the current HIV diagnostic testing algorithm, please refer to <https://stacks.cdc.gov/view/cdc/50872>.
- In the absence of laboratory tests, record HIV infection or stage 3 (AIDS) diagnostic evidence documented in the chart by a physician.
- For children reported as perinatally exposed to HIV, record all test results of tests performed to determine the diagnostic status of the child.

#### 9.1 HIV IMMUNOASSAYS (IA)

- Assuming active case finding, review patient’s chart and laboratory reports for the earliest date of documented HIV positivity.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
  - Enter specimen collection date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
- Enter testing option for all tests. (**Optional**, applies to health department & health care providers)
  - Enter “Point-of-care test by provider” if the test was performed by the provider either in a healthcare setting or other testing venue.
  - Enter “Self-test, result directly observed by provider” if the test was performed by the patient but directly observed by a provider (including via a telemedicine appointment).
  - Enter “Lab-test, self-collected sample” if the patient collected the sample (blood or oral fluid) and sent it to the laboratory for testing.

##### 9.1.1 HIV-1 IA

- Enter result and collection date of first HIV-1 IA. (**Required**, applies to health department & health care providers)
- “Positive IA” means a result of repeatedly reactive on a single sample.

##### 9.1.2 HIV-1/2 IA

- Enter result and date of first HIV-1/2 IA. (**Required**, applies to health department & health care providers)
- “Positive IA” means a result of repeatedly reactive on a single sample.

##### 9.1.3 HIV-1/2 AG/AB

- Enter result and collection date of first HIV-1/2 combination IA test. (**Required**, applies to health department & health care providers)
- “Positive IA” means a result of repeatedly reactive on a single sample.

##### 9.1.4 HIV-2 IA

- Enter result and collection date of first HIV-2 IA. (**Required**, applies to health department & health care providers)
  - “Positive IA” means a result of repeatedly reactive on a single sample.
- 9.1.5 HIV-1/2 AG/AB-DIFFERENTIATING IMMUNOASSAY
- Enter collection date of first HIV-1/2 Ag/Ab-Differentiating IA. (**Required**, applies to health department & health care providers)
  - Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
  - Record the result for each analyte (HIV-1 Ag and HIV-1/2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1/2 Ab result. (**Required**, applies to health department & health care providers)
- 9.1.6 HIV-1/2 AG/AB AND TYPE-DIFFERENTIATING IMMUNOASSAY
- Enter collection date of first HIV-1/2 Ag/Ab and Type-Differentiating IA. (**Required**, applies to health department & health care providers)
  - Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
  - If provided, enter index value for the overall interpretation. (**Optional**, applies to health department & health care providers)
  - Record the result for each analyte (HIV-1 Ag and HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)
  - Enter the index value for each analyte. (**Optional**, applies to health department & health care providers)
- 9.1.7 HIV-1/2 TYPE-DIFFERENTIATING IMMUNOASSAY (supplemental)
- Enter collection date of first HIV-1/2 Type-Differentiating IA. (**Required**, applies to health department & health care providers)
  - Enter the overall interpretation of the test. (**Required**, applies to health department & health care providers)
  - Record the result for each analyte (HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)
- 9.1.8 HIV-1 WESTERN BLOT
- Enter the result and collection date of first HIV-1 western blot. (**Required**, applies to health department & health care providers)
  - Western blot banding patterns should be interpreted according to the CDC/Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) recommendations *Interpretation and use of the western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections*. MMWR Suppl. 1989 Jul 21;38(7):1-7. PMID: 2501638.
- 9.1.9 HIV-1 IFA
- Enter the result and collection date of first HIV-1 IFA. (**Required**, applies to health department & health care providers)
- 9.1.10 HIV-2 WESTERN BLOT
- Enter the result and collection date of first HIV-2 western blot. (**Required**, applies to health department & health care providers)

## 9.2 HIV DETECTION TESTS

- All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as an immunoassay or western blot establish the presence of the immune system's response to the pathogen (i.e., HIV antibodies).
  - Assuming active case finding, review patient's chart and laboratory reports for the earliest date of documented HIV positivity.
  - Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
  - Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
    - Enter specimen collection date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
  - Enter testing option for all tests. (**Optional**, applies to health department & health care providers)
    - Enter “Point-of-care test by provider” if the test was performed by the provider either in a healthcare setting or other testing venue.
    - Enter “Self-test, result directly observed by provider” if the test was performed by the patient but directly observed by a provider (including via a telemedicine appointment).
    - Enter “Lab-test, self-collected sample” if the patient collected the sample (blood or oral fluid) and sent it to the laboratory for testing.
- 9.2.1 HIV-1/2 RNA NAAT (QUALITATIVE)
- Enter result and collection date of earliest nucleic acid amplification test (NAAT). (**Required**, applies to health department & health care providers)
- 9.2.2 HIV-1 RNA NAAT (QUALITATIVE and QUANTITATIVE)
- Enter the collection date of earliest NAAT. (**Required**, applies to health department & health care providers)
  - Enter the qualitative result of the test. (**Required**, applies to health department & health care providers)
  - For all reactive qualitative results, record the result for the analyte (quantitative result). (**Required**, applies to health department & health care providers)
    - Where results are reported as “Detected” above the limit of quantification (LOQ), select “Detectable above limit” and the result value in the copies/mL field. For example, a result of “>10,000,000 cp/mL detected” should be entered into the copies/ml field as “greater than detectable by this assay - 10,000,000 cp/mL”.
    - Where results are reported as “Detected”, select “Detectable within limits” and the result value in the copies/mL field.
    - Where the results reported as “Detected” below the LOQ, select “Detectable below limit” and the result value in the copies/mL field. For example, a result of “<20 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 20 cp/mL”.
- 9.2.3 HIV-1 RNA/DNA NAAT (QUALITATIVE)
- Enter result and collection date of earliest NAAT. (**Required**, applies to health department & health care providers)
- 9.2.4 HIV-1 Culture
- Enter result and collection date of earliest culture result. (**Required**, applies to

health department & health care providers)

9.2.5 HIV-2 RNA/DNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest NAAT. (**Required**, applies to health department & health care providers)

9.2.6 HIV-2 Culture

- Enter result and collection date of earliest culture result. (**Required**, applies to health department & health care providers)

9.2.7 HIV-1 RNA/DNA NAAT (QUANTITATIVE)

- Enter date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the result of the test. (**Required**, applies to health department & health care providers)
  - Where results are reported as “Detected” above the limit of quantification (LOQ), select “Detectable above limit” and the result value in the copies/mL field. For example, a result of “>10,000,000 cp/mL detected” should be entered into the copies/ml field as “greater than detectable by this assay - 10,000,000 cp/mL”.
  - Where results are reported as “Detected”, select “Detectable within limits” and the result value in the copies/mL field.
  - Where the results reported as “Detected” below the LOQ, select “Detectable below limit” and the result value in the copies/mL field. For example, a result of “<20 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 20 cp/mL”.
  - Where the results reported as “Not detected”, select “Not detected”.

9.2.8 HIV-2 RNA/DNA NAAT (QUANTITATIVE)

- Enter date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the result of the test. (**Required**, applies to health department & health care providers)
  - Where results are reported as “Detected” above the limit of quantification (LOQ), select “Detectable above limit” and the result value in the copies/mL field. For example, a result of “>10,000,000 cp/mL detected” should be entered into the copies/ml field as “greater than detectable by this assay - 10,000,000 cp/mL”.
  - Where results are reported as “Detected”, select “Detectable within limits” and the result value in the copies/mL field.
  - Where the results reported as “Detected” below the LOQ, select “Detectable below limit” and the result value in the copies/mL field. For example, a result of “<20 cp/mL detected” should be entered into the copies/ml field as “fewer than detectable by this assay - 20 cp/mL”.
  - Where the results reported as “Not detected”, select “Not detected”.

9.3 DRUG RESISTANCE TESTS (GENOTYPIC)

- This section should be completed if there is evidence of a drug resistance test (genotypic), regardless of the type of drug resistance test, in the patient’s medical or other record.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter the collection date of the earliest test. (**Required**, applies to health department & health care providers)

- When entering this information in eHARS, you should use the “Lab Data” tab and choose “HIV-1 Genotype (Unspecified)” as the test type. You will not be able to enter a genotype sequence since this test type only captures evidence of a drug resistance test (genotypic). If a corresponding genotype sequence is subsequently received, you should import this information as a separate laboratory document using the test type that reflects the type of drug resistance test that was conducted (e.g., HIV-1 Genotype (PR/RT RNA Nucleotide Sequence-Sanger method)).

#### 9.4 IMMUNOLOGIC TESTS (CD4 COUNT AND PERCENTAGE)

- Enter the results of *all* HIV-related CD4 tests that are available from the source where information is being collected to complete the form. At minimum, the first CD4 results closest to the date of initial HIV infection diagnosis should be reported and the first CD4 results indicative of stage 3 (AIDS) should be reported if available.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Whenever CD4 count and percentage are both available for the same specimen collection date, record both.
- Enter specimen collection date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03/./2011). (**Required**, applies to health department & health care providers)

##### 9.4.1 CD4 COUNT

- Enter result and specimen collection date of all CD4 counts. (**Required**, applies to health department & health care providers)

##### 9.4.2 CD4 PERCENTAGE

- Record result and specimen collection date of all CD4 percentages. (**Required**, applies to health department & health care providers)

#### 9.5 DOCUMENTATION OF TESTS

##### 9.5.1 DID DOCUMENTED LABORATORY TEST RESULTS MEET APPROVED HIV DIAGNOSTIC ALGORITHM CRITERIA? (**Required** if applicable, applies to health department & health care providers)

- This section captures diagnoses through novel algorithms and should only be completed if none of the following were positive for **HIV-1**: western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen test, or nucleotide sequence.
- HIV-1 antigen analyte results from combination antigen/antibody tests in which the antigen result can be differentiated from the antibody result, such as an “HIV-1/2 Ag/Ab differentiating immunoassay” or an “HIV-1/2 Ag/Ab and type-differentiating immunoassay”, are *not* considered stand-alone p24 antigen tests. Refer to sections 9.1.5 and 9.1.6 for more information regarding combination Ag/Ab IA.
- “Yes” indicates that the test results were determined to be part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2 (refer to the most recent case definition for HIV infection available at <https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/>), regardless of whether the tests were approved for other purposes such as laboratory-based HIV testing or point-of-care HIV screening.
  - If “Yes”, enter date of earliest positive test result for this algorithm in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03/./2011). (**Required** if applicable, applies to health department & health care providers)

providers).

- “No” indicates that the test results were determined to *not* be a part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2.
- “Unknown” indicates that you are unable to determine whether the test results were part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2.
- Values of “No” and “Unknown” should generally not be selected. This form is intended to be used to ascertain that two tests *are* part of an algorithm that meet the HIV surveillance case definition. Carefully review all “No” and “Unknown” responses before entering into the surveillance system.

9.5.2 IS EARLIEST EVIDENCE OF DIAGNOSIS DOCUMENTED BY A PHYSICIAN RATHER THAN BY LABORATORY TEST RESULTS? (**Required** if applicable, applies to health department & health care providers)

- If laboratory evidence of an HIV test is unavailable or was insufficient to meet surveillance case definition in the patient’s medical or other record and written documentation of laboratory evidence of HIV infection consistent with the HIV case definition is noted by the physician, enter “Yes”; otherwise enter “No” or “Unknown”.

9.5.2.1 HIV-INFECTED (**Required** if applicable, applies to health department & health care providers)

- IF “YES” TO 9.5.2.1, PROVIDE DATE OF DIAGNOSIS BY PHYSICIAN (**Required** in the absence of laboratory results, applies to health department & health care providers)
- Date of diagnosis is defined as the date (at least the year) of diagnosis reported in the content of the medical record. If the diagnosis date was not reported in the note, the date when the note was written can be used as a proxy. For example, if a health care provider writes a note in a medical chart on 4/10/2010 stating the patient had received a diagnosis of HIV infection on 2/11/2010, then 2/11/2010 should be recorded as the date of diagnosis by the physician.

9.5.2.2 NOT HIV-INFECTED (**Required** if applicable, applies to health department & health care providers)

- IF “YES” TO 9.5.2.2, PROVIDE DATE OF DIAGNOSIS BY PHYSICIAN (**Required** in the absence of laboratory results, applies to health department & health care providers)
- Date of diagnosis is defined as the date (at least the year) when the patient was determined to be “not HIV-infected”.

## 10. Birth History (for patients exposed perinatally with or without consequent infection)

### X. Birth History (for patients exposed perinatally with or without consequent infection)

Birth history available? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown						
Residence at Birth <input type="checkbox"/> Check if <u>SAME</u> as current address						
Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary						
*Street Address				City		
County			State/Country		*ZIP Code	
Facility of Birth <input type="checkbox"/> Check if <u>SAME</u> as facility providing information						
Facility Name of Birth (if child was born at home, enter "home birth")					*Phone ( )	
Facility Type <u>Inpatient:</u> <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ <u>Outpatient:</u> <input type="checkbox"/> Other, specify _____ <u>Other Facility:</u> <input type="checkbox"/> Emergency room <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____						
*Street Address				City		
County			State/Country		*ZIP Code	
Birth History		Birth Weight _____ lbs _____ oz _____ grams		Type <input type="checkbox"/> 1-Single <input type="checkbox"/> 2-Twin <input type="checkbox"/> 3-More than two <input type="checkbox"/> 9-Unknown		
Delivery <input type="checkbox"/> Vaginal <input type="checkbox"/> Cesarean <input type="checkbox"/> Unknown						
If Cesarean delivery, mark all the following indications that apply.						
<input type="checkbox"/> HIV indication (high viral load) <input type="checkbox"/> Previous Cesarean (repeat) <input type="checkbox"/> Malpresentation (breech, transverse) <input type="checkbox"/> Prolonged labor or failure to progress <input type="checkbox"/> Birthing person's or physician's preference <input type="checkbox"/> Fetal distress <input type="checkbox"/> Placenta abruptia or p. previa <input type="checkbox"/> Other (e.g., herpes, disproportion) (Specify) _____ <input type="checkbox"/> Not specified						
Birth Information		Date		Time (use military time: noon = 12:00; midnight = 00:00)		
Rupture of membranes		_____ / _____ / _____		_____ : _____		
Delivery		_____ / _____ / _____		_____ : _____		
Congenital Disorders <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If YES, specify types						
Neonatal Status <input type="checkbox"/> 1-Full-term <input type="checkbox"/> 2-Premature <input type="checkbox"/> 9-Unknown			Neonatal Gestational Age in Weeks _____ (99 = Unknown, 00 = None)			
Was a toxicology screen done on the infant after birth? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If screening for the same substance was done on more than one occasion, record additional dates and results in Comments)		Not screened		Date of screen		Result
						Positive
						Negative
						Unknown
		Alcohol		_____ / _____ / _____		<input type="checkbox"/>
		Amphetamines		_____ / _____ / _____		<input type="checkbox"/>
		Barbiturates		_____ / _____ / _____		<input type="checkbox"/>
		Benzodiazepines		_____ / _____ / _____		<input type="checkbox"/>
		Cocaine		_____ / _____ / _____		<input type="checkbox"/>
		Crack cocaine		_____ / _____ / _____		<input type="checkbox"/>
		Fentanyl		_____ / _____ / _____		<input type="checkbox"/>
		Hallucinogens		_____ / _____ / _____		<input type="checkbox"/>
		Heroin		_____ / _____ / _____		<input type="checkbox"/>
		K2		_____ / _____ / _____		<input type="checkbox"/>
		Marijuana (cannabis, THC, cannabinoids)		_____ / _____ / _____		<input type="checkbox"/>
		Methadone		_____ / _____ / _____		<input type="checkbox"/>
		Methamphetamines		_____ / _____ / _____		<input type="checkbox"/>
Nicotine (any tobacco)		_____ / _____ / _____		<input type="checkbox"/>		
Opiates		_____ / _____ / _____		<input type="checkbox"/>		
PCP		_____ / _____ / _____		<input type="checkbox"/>		
Other (specify) _____		_____ / _____ / _____		<input type="checkbox"/>		
Specific drug(s) not documented		_____ / _____ / _____		<input type="checkbox"/>		

- Birth history information is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
- Enter the data below for all children reported as perinatally exposed with or without consequent HIV infection.

#### 10.1 BIRTH HISTORY AVAILABLE (**Optional**, applies to health department & health care providers)

- If none of the birth history elements in the section are available, proceed to next section, Birthing Person History.

#### 10.2 RESIDENCE AT BIRTH (**Required**, applies to health department & health care providers)

- Select one of the address types for the patient's residence at time of birth.
- Enter the street address, city, county, state, country name, and zip code of the patient's residence at time of birth

#### 10.3 FACILITY OF BIRTH (**Optional**, applies to health department & health care providers)

- Check if same as facility providing information.

- Enter name, address, phone, city, county, state/country and zip code of the hospital/clinic of birth.
- Sites should uniformly record hospital names, including abbreviations.
- If this child was born at home, enter “home birth”.

#### 10.4 BIRTH HISTORY

- 10.4.1 BIRTH WEIGHT (**Optional**, applies to health department & health care providers)
  - Enter the birth weight in pounds and ounces, or grams.
- 10.4.2 TYPE (**Optional**, applies to health department & health care providers)
  - Select applicable response. If unknown, select “9”.
- 10.4.3 DELIVERY (**Required**, applies to health department & health care providers)
  - Select the applicable response.
  - Notes in the child’s records are acceptable even if no birth records are available.
  - If search for this datum was completed and the delivery method could not be determined or if the delivery method was documented to be unknown, select “Unknown”.
- 10.4.4 IF CESAREAN DELIVERY, MARK ALL THE FOLLOWING INDICATIONS THAT APPLY (**Required**, if applicable, applies to health department & health care providers)
  - Select the applicable indications.
  - The reason(s) for a cesarean delivery should be documented in the labor and delivery medical record. Notes in the child’s records are acceptable even if no birth records are available.
  - If search for this datum was completed and the indications could not be determined, select “Not specified”.
- 10.4.5 BIRTH INFORMATION (**Required**, if applicable, applies to health department & health care providers)
  - This information may be listed in the labor and delivery record or in a dictated/transcribed labor and delivery summary by the physician. Write time in military hours (e.g., 9:15 a.m. is 09:15, 1:00 p.m. is 13:00). Midnight is 00:00 and noon is 12:00. To calculate military time, count the number of hours and minutes after midnight or 00:00 hours. Enter the date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
    - Rupture of membranes information should be found on the labor and delivery summary sheet. The date and time are necessary to calculate the duration of ruptured membranes and duration of labor. Rupture of membranes refers to the time when the amniotic sac is either purposely broken or ruptures on its own. When a physician/health care provider ruptures the membranes this is referred to as artificial rupture of membranes--often abbreviated as AROM. When membranes rupture on their own, spontaneously, this is referred to as spontaneous rupture of membranes (SROM). Premature rupture of membranes is referred to as PROM. In the case of cesarean section, the rupture of membranes may be almost concurrent with time of delivery.
    - Delivery information should be found on the labor and delivery summary sheet. The date and time are necessary to calculate the duration of ruptured membranes and duration of labor. If the time of delivery is unknown because of a home or out-of-hospital delivery, enter “...”. Verify that the delivery date is the same as the date of birth noted on the



first page of the abstraction form. If there is an inconsistency, verify the correct date of birth and update eHARS if necessary.

- 10.4.6-10.4.7 CONGENITAL DISORDERS and IF YES, SPECIFY TYPES (**Optional**, applies to health department & health care providers)
- If “Yes”, specify type.
  - Refer to [Appendix 10.4.6](#) for further guidance.
- 10.4.8 NEONATAL STATUS (**Optional**, applies to health department & health care providers)
- Select applicable response and record the child’s gestational age, if known, in the boxes provided.
  - “Full term” is defined as gestational age greater than or equal to 37 weeks.
  - “Premature” is defined as gestational age less than 37 weeks.
  - If search for gestational age was unsuccessful, then enter “99” for unknown number of weeks.
  - Post mature neonatal status (after 40 weeks) should be recorded as full term.
  - If search for this datum was completed and the gestational age cannot be determined, select “Unknown”.
- 10.4.8.1 NEONATAL GESTATIONAL AGE IN WEEKS
- Enter weeks of gestation.
  - If search for gestational age was unsuccessful, then enter “99” for unknown number of weeks.
- 10.4.9 WAS A TOXICOLOGY SCREEN DONE ON THE INFANT AFTER BIRTH (**Recommended**, if applicable, applies to health department & health care providers)
- Select applicable response. Include any toxicology screen with a specimen collection date on the child’s date of birth or within the 6 days following the child’s date of birth.
  - If search for this datum was completed but a response of “Yes” or “No” cannot be determined, select “Unknown”.
  - Most toxicology screens on infants are done using urine. A positive screen at birth indicates drug use by the birthing person before delivery. This information should be noted in the infant’s birth chart.
  - If the specimen for any toxicology screen was collected for the infant on the date of birth or the following 6 days after birth, complete the following information for each substance.
    - If the substance was not included in any toxicology screen in the 7 days on or after the child’s date of birth, select “Not screened” for the particular substance.
    - If the substance was included in any toxicology screen in the 7 days on or after the child’s date of birth, enter the date of screen for the substance in mm/dd/yyyy format using “.” for unknown values (e.g., 03././2011) and select the applicable result; select “Unknown” if a search for the result was completed but the result was not documented.
    - If the same substance was screened more than one time during the 7 days on or after the child’s date of birth, enter the subsequent date of screen and result values in the Comments section. In eHARS, enter the additional information on the PCRF on the “Birth History” tab.
    - If screening for ‘Other’ substance was done, specify the substance in the space provided.

# 11. Birthing Person History

## XI. Birthing Person History (for patients exposed perinatally with or without consequent infection)

Birthing Person Date of Birth ____/____/____		Birthing Person Last Name Soundex																																																									
Birthing Person Country of Birth		Birthing Person State ID Number																																																									
Birthing Person City/County ID Number		*Other Birthing Person ID (specify type of ID and ID number)																																																									
Prenatal Care—Month of Pregnancy Prenatal Care Began (99 = Unknown, 00 = None)		Prenatal Care—Total Number of Prenatal Care Visits (99 = Unknown, 00 = None)																																																									
Has the birthing person ever been pregnant before this pregnancy? Include previous pregnancies that ended in a live birth, miscarriage, stillbirth, or induced abortion. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown																																																											
If YES, specify how many previous pregnancies _____ <table border="0"> <tr> <td></td> <td>Live birth</td> <td>Miscarriage or Stillbirth</td> <td>Induced abortion</td> <td>Year outcome occurred (9999 = Unknown)</td> </tr> <tr> <td>i.</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>_____</td> </tr> <tr> <td>ii.</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>_____</td> </tr> <tr> <td>iii.</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>_____</td> </tr> <tr> <td>iv.</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>_____</td> </tr> <tr> <td>v.</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>_____</td> </tr> </table>					Live birth	Miscarriage or Stillbirth	Induced abortion	Year outcome occurred (9999 = Unknown)	i.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	ii.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	iii.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	iv.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	v.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																										
	Live birth	Miscarriage or Stillbirth	Induced abortion	Year outcome occurred (9999 = Unknown)																																																							
i.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																																							
ii.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																																							
iii.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																																							
iv.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																																							
v.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____																																																							
(Record additional pregnancy outcomes in Comments)																																																											
Was a test result (with a specimen collection date within the 6 weeks on or before delivery) documented in the birthing person's labor/delivery record CD4 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown      Quantitative NAAT (RNA or DNA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown																																																											
Did birthing person receive any antiretrovirals (ARVs) prior to this pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown Date began ____/____/____      Date of last use ____/____/____																																																											
If YES, specify all ARVs _____																																																											
Did birthing person receive any ARVs during this pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown Date began ____/____/____      Date of last use ____/____/____																																																											
If YES, specify all ARVs _____																																																											
If NO, select reason <input type="checkbox"/> No prenatal care <input type="checkbox"/> Birthing person known to be HIV-negative during pregnancy <input type="checkbox"/> Unknown <input type="checkbox"/> HIV serostatus of birthing person unknown <input type="checkbox"/> Other (specify) _____																																																											
Did birthing person receive any ARVs during labor/delivery? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Unknown Date began ____/____/____      Date of last use ____/____/____																																																											
If YES, specify all ARVs _____																																																											
If NO, select reason <input type="checkbox"/> Precipitous delivery/STAT Cesarean delivery <input type="checkbox"/> HIV serostatus of birthing person unknown <input type="checkbox"/> Birth not in hospital <input type="checkbox"/> Birthing person tested HIV negative during pregnancy <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Unknown																																																											
Was the birthing person screened for any of the following conditions during this pregnancy? Check test(s) performed before birth																																																											
	Yes	Date of screen (mm/dd/yyyy)	No	Unknown																																																							
Group B strep	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>																																																							
Hepatitis B (HBsAg)	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>																																																							
Rubella	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>																																																							
Syphilis	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>																																																							
Were any of the following conditions diagnosed for the birthing person during this pregnancy or at the time of labor and delivery? <table border="0"> <tr> <td></td> <td>Yes</td> <td>Date of diagnosis (mm/dd/yyyy)</td> <td>No</td> <td>Unknown</td> </tr> <tr> <td>Bacterial vaginosis</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Chlamydia trachomatis infection</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Genital herpes</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Gonorrhea</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Group B strep</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Hepatitis B (HBsAg)</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Hepatitis C</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>PID</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Syphilis</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Trichomoniasis</td> <td><input type="checkbox"/></td> <td>____/____/____</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>						Yes	Date of diagnosis (mm/dd/yyyy)	No	Unknown	Bacterial vaginosis	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Chlamydia trachomatis infection	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Genital herpes	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Gonorrhea	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Group B strep	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Hepatitis B (HBsAg)	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Hepatitis C	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	PID	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Syphilis	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	Trichomoniasis	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>
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Bacterial vaginosis	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>																																																							
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Trichomoniasis	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>																																																							
Were substances used by the birthing person during this pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown																																																											
	Used and injected	Used and did not inject	Used and unknown if injected	Did not use	Unknown if used																																																						
Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Barbiturates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Crack cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Fentanyl	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Hallucinogens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Heroin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
K2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Marijuana (cannabis, THC, cannabinoids)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Methamphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Nicotine (any tobacco)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Opiates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
PCP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Other (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						
Specific drug(s) not documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																						

## XI. Birthing Person History (for patients exposed perinatally with or without consequent infection) (cont)

Was a toxicology screen done on the birthing person (either during this pregnancy or at the time of delivery)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If screening for the same substance was done on more than one occasion, record additional dates and results in Comments)					
	Not screened	Date of screen	Positive	Negative	Unknown
Alcohol	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamines	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturates	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crack cocaine	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fentanyl	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hallucinogens	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heroin	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
K2	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (cannabis, THC, cannabinoids)	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamines	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine (any tobacco)	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCP	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify) _____	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specific drug(s) not documented	<input type="checkbox"/>	____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Birthing person history is for state and local health department use only and is not transmitted to CDC if marked with an \* on the form.
  - Enter the data below regarding the birthing person for all children reported as perinatally exposed with or without consequent HIV infection. If information for the birthing person is not available (e.g., because child is adopted), proceed to the next section, Treatment/Services Referrals.
- 11.1 BIRTHING PERSON DATE OF BIRTH (**Optional**, applies to health department & health care providers)
- Enter the birthing person's date of birth in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 11.2 BIRTHING PERSON LAST NAME SOUNDEX (**Optional**, applies to health department)
- After the birthing person's last name is entered into eHARS, the software automatically generates this variable by using the birthing person's last name. After the code is generated, health department staff should fill in this field on the form.
  - This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name SounDEX is created. You can access the *eHARS Technical Reference Guide* through SharePoint: <https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>
- 11.3 BIRTHING PERSON COUNTRY OF BIRTH (**Optional**, applies to health department & health care providers)
- Select applicable response.
  - For birthing persons born in US minor outlying areas, specify the name of the US dependency from the following table:
- | US Dependencies |                |
|-----------------|----------------|
| Baker Island    | Midway Islands |
| Howland Island  | Navassa Island |
| Jarvis Island   | Palmyra Atoll  |
| Johnston Atoll  | Wake Island    |
| Kingman Reef    |                |
- For birthing persons born in any other area outside of the US and US minor outlying areas, specify the country name.
  - If this information is not available in the child's records, it can be left blank and updated on follow-up.
- 11.4 BIRTHING PERSON STATE ID NUMBER (**Optional**, applies to health department)
- Enter assigned state number if the birthing person is known to be HIV infected.
  - State numbers should not be reused.
- 11.5 BIRTHING PERSON CITY/COUNTY ID NUMBER (**Optional**, applies to health department)
- Enter the assigned city/county number if the birthing person is known to be HIV infected.
  - City/County numbers should not be reused.
- 11.6 OTHER BIRTHING PERSON ID (**Optional**, applies to health department & health care providers).
- Enter any other ID type (such as social security number) for the birthing person and the number of the other ID.
- 11.7 PRENATAL CARE
- Prenatal care is defined as any care for the pregnancy beyond pregnancy testing and before delivery, even if no regular follow-up ensued.

11.7.1 MONTH OF PREGNANCY PRENATAL CARE BEGAN (**Optional**, applies to health department & health care providers)

- Record the gestational month of pregnancy (01 to 09) that the birthing person began prenatal care. A prenatal care visit is the first visit where intake information is obtained. Normally a birthing person knows they is pregnant at the time of this first prenatal care visit. A visit to a doctor to confirm pregnancy status would not be considered the first prenatal care visit unless intake data and other services typical of the first prenatal care visit are obtained at the time of that confirmation. Such services would include intake prenatal blood tests, for example. If the birthing person had been seen by more than one prenatal care provider, then the date of the visit to the first prenatal care provider seen should be documented.
- If any fraction of a month is reported, round to the next whole month.
- In the absence of prenatal care, enter “00”.
- If search for this datum was unsuccessful, then enter “99” for month of first visit.
- If entry is reported in weeks, convert to appropriate months as follows:

Weeks	Months	Weeks	Months
1–4	1	22–26	6
5–8	2	27–30	7
9–13	3	31–35	8
14–17	4	36–40	9
18–21	5	41+	10

- Abstractors should use the gestational age value available in the record. The method (LMP, ultrasound, infant exam) for assigning gestational age in the medical record might vary.

11.7.2 TOTAL NUMBER OF PRENATAL CARE VISITS (**Optional**, applies to health department & health care providers)

- Record the total number of times the birthing person went to the clinic or doctor for prenatal care; exclude visits unrelated to prenatal care.
- In the absence of prenatal care visits, enter “00”.
- In the presence of prenatal care and search for this datum was unsuccessful, then enter “99” for number of prenatal visits.
- Where data source reports a range of visits (e.g., “10–13”), enter the lowest number (e.g., “10”).

11.8 HAS THE BIRTHING PERSON EVER BEEN PREGNANT BEFORE THIS PREGNANCY (**Optional**, if applicable, applies to health department & health care providers)

- Select applicable response. If search for this datum was completed but a response of “Yes” or “No” cannot be determined, select “Unknown”.

11.8.1 IF YES, NUMBER OF PREVIOUS PREGNANCIES (**Optional**, if applicable, applies to health department & health care providers)

- This number should include all pregnancies, regardless of outcome (e.g., including abortions and miscarriages) up to but EXCLUDING the pregnancy that is being abstracted.

11.8.2. PREGNANCY OUTCOME (**Optional**, if applicable, applies to health department & health care providers)

- For each previous pregnancy where the pregnancy outcome is known, select the applicable response.

- Live birth includes preterm and term births
  - Miscarriage or stillbirth includes spontaneous abortions/fetal deaths that occur before 20 weeks (miscarriage) or after 20 weeks (stillbirth).
  - Induced abortion includes abortions brought on purposely and may also be known as an ‘artificial’ or ‘therapeutic’ abortion (TAB) or referred to as a ‘termination of pregnancy’ (TOP). the chart may abbreviate this as ‘A’ or ‘Ab’ or ‘TAB’ or ‘TOP’ followed by a number designating the number of abortions prior to this pregnancy.
  - If there are more than 5 previous pregnancies, record the additional information in the Comments section. In eHARS, record additional pregnancies on the PCRf on the “Birthing Person History” tab.
- 11.8.3 YEAR OUTCOME OCCURRED (**Optional**, if applicable, applies to health department & health care providers)
- For each previous pregnancy where the pregnancy outcome is known, record the four-digit year associated with the pregnancy outcome.
  - If the year of the pregnancy outcome is unknown, enter “9999”.
  - If there are more than 5 previous pregnancies, record the additional information in the Comments section. In eHARS, record additional pregnancies on the PCRf on the “Birthing Person History” tab.
- 11.9 WAS A TEST RESULT (WITH A SPECIMEN COLLECTION DATE WITHIN THE 6 WEEKS ON OR BEFORE DELIVERY) DOCUMENTED IN THE BIRTHING PERSON’S LABOR/DELIVERY RECORD (**Optional**, applies to health department and health care providers)
- Select applicable response for both the CD4 and quantitative NAAT (RNA or DNA) test types.
  - Limited to test results with specimens collected within the 6 weeks on or before delivery.
  - If a search for this datum was completed but a response of “Yes” or “No” cannot be determined, select “Unknown”
- 11.10 DID BIRTHING PERSON RECEIVE ANTIRETROVIRALS (ARVs) PRIOR TO THIS PREGNANCY? (**Recommended**, applies to health department & health care providers)
- ‘Pregnancy’ is defined as: The condition of having a developing embryo or fetus in the body after union of an ovum and spermatozoon. Labor and delivery occur after this interval, so they are not considered part of the ‘pregnancy’.
  - Select “Yes” if information is available that states that the birthing person used ARVs prior to this pregnancy. If “Yes”, record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
  - Select “No” if the birthing person did not use ARVs prior to this pregnancy.
  - If a birthing person did not receive ARVs, do not assume it was because they refused. Select “Refused” only if explicit documentation in the medical record indicates that the birthing person was offered the drug, but the birthing person declined.
  - Select “Unknown” after an unsuccessful search for this datum.
- 11.10.1 IF “YES”, PLEASE SPECIFY ALL
- Record all ARVs received prior to this pregnancy.
- 11.11 DID BIRTHING PERSON RECEIVE ARVs DURING PREGNANCY? (**Required**, applies to health department & health care providers)
- Select “Yes” if information is available that states that the birthing person used ARVs any time during pregnancy. If “Yes”, record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03../2011).
  - Select “No” if the birthing person did not use ARVs during pregnancy.

- Select “Refused” only if explicit documentation in the medical record indicates that the birthing person was offered the drug, but the birthing person declined.
- Select “Unknown” if it is unknown whether the birthing person ever used ARVs during pregnancy.

11.11.1 IF “YES”, PLEASE SPECIFY ALL

- Record all ARVs received during pregnancy.
- For additional information about antiretroviral regimens for pregnant patients with HIV infection refer to *Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States* at [https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal\\_GL.pdf](https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf).

11.11.2 IF NO, SELECT REASON

- Select “No prenatal care” if the birthing person did not receive any prenatal care during pregnancy.
- Select “Birthing person known to be HIV-negative during pregnancy” if the birthing person tested HIV negative during pregnancy and no further testing was documented. There must be evidence of a negative test during pregnancy in the chart; do not use patient report.
- Select “HIV serostatus of birthing person unknown” if the physician did not know the HIV status of the birthing person because the birthing person refused testing or the physician did not offer testing during pregnancy.
- Select “Other” if another reason for not receiving ARVs was documented. If “Other” is selected specify the specific reason.
- Select “Unknown” after an unsuccessful search for this datum.
- If more than one reason applies, enter the additional reason(s) in the Comments section. In eHARS, enter each reason on a separate PCRF document.

11.12 DID BIRTHING PERSON RECEIVE ARVs DURING LABOR/DELIVERY? (**Required**, applies to health department & health care providers)

- Select “Yes” if information is available that states that the birthing person used ARVs any time during labor/delivery. Labor and delivery period is also termed the intrapartum period and refers to the time from which the person was admitted to the hospital for labor to the time of delivery. If “Yes”, record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
- Select “No” if the birthing person did not use ARVs during labor/delivery.
- Select “Refused” only if explicit documentation in the medical record indicates that the birthing person was offered the drug, but the birthing person declined.
- Select “Unknown” if it is unknown whether the birthing person ever used ARVs during labor/delivery.

11.12.1 IF “YES”, PLEASE SPECIFY ALL

- Record all ARVs received during labor/delivery.
- For additional information about antiretroviral regimens during the intrapartum period refer to *Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States* at [https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal\\_GL.pdf](https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf).

11.12.2 IF NO, SELECT REASON

- Select “Precipitous delivery/STAT Cesarean delivery” if an eminent delivery of an infant may preclude prescription and/or administration of ARV to the birthing



person.

- Select “HIV serostatus of birthing person unknown” if the physician did not know the HIV status of the birthing person because the birthing person refused testing or the physician did not offer testing during pregnancy.
- Select “Birth not in hospital” if the birth occurred outside a hospital; in all likelihood ARV would not have been administered.
- Select “Birthing person tested HIV negative during pregnancy” if the birthing person tested HIV negative during pregnancy and no further testing was documented. There must be evidence of a negative test during pregnancy in the chart; do not use patient report.
- Select “Other” if another reason for not receiving ARVs was documented. If “Other” is selected specify the specific reason.
- Select “Unknown” after an unsuccessful search for this datum.
- If more than one reason applies, enter the additional reason(s) in the Comments section. In eHARS, enter each reason on a separate PCRF document.

11.13 WAS THE BIRTHING PERSON SCREENED FOR ANY OF THE FOLLOWING CONDITIONS DURING THIS PREGNANCY (**Recommended**, applies to health department & health care providers)

- Select “Yes” if the birthing person was screened for the condition during this pregnancy. If screened, enter the date of the screening; if a sample was drawn for the screening use the date of specimen collection. Enter date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011). If the birthing person was screened for the same condition more than once during this pregnancy, enter the additional screening dates in the Comments section. In eHARS, enter the additional screening information on the PCRF on the “Birthing Person History” tab.
- Select “No” if the birthing person was not screened for the condition during this pregnancy.
- Select “Unknown” after an unsuccessful search for this datum.
- Refer to [Appendix 11.13](#) for additional information about each condition.

11.14 WERE ANY OF THE FOLLOWING CONDITIONS DIAGNOSED FOR THE BIRTHING PERSON DURING THIS PREGNANCY OR AT THE TIME OF LABOR AND DELIVERY (**Recommended**, applies to health department & health care providers)

- For this question, “diagnosed” refers to newly diagnosed, a recurrence of, or a chronic infection with any of the following conditions. Screening for syphilis, gonorrhea, and chlamydia is typically done during prenatal care. Generally, diagnosis of an STD/STI will be documented in multiple places in the chart including progress notes, a prenatal clinic visit summary sheet (which should include summary of laboratory tests for various sexually transmitted diseases), laboratory results section, or in sexually transmitted disease summary sheets (typical in public health clinics).
- Diagnoses may be presumptive or definitive depending on symptoms and laboratory tests. If a diagnosis is made either presumptively or definitively, note the answer as “Yes”. For specific criteria for answering “Yes” to this question refer to [Appendix 11.14](#). If diagnosed, enter the date of diagnosis; if the diagnosis was based on test results, use the date of specimen collection for the date of diagnosis. Enter date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011). If the same condition was diagnosed for the birthing person more than once during this pregnancy, enter the additional diagnosis dates in the Comments section. In eHARS, enter the additional diagnosis information on the PCRF on the “Birthing Persons History” tab.
- Select “No” if evidence that the birthing person was screened for the condition during pregnancy but the condition was not diagnosed.
- Select “Unknown” after unsuccessful search for this datum.

11.15 WERE SUBSTANCES USED BY THE BIRTHING PERSON DURING THIS PREGNANCY (**Recommended**, applies to health department & health care providers)

- Indicate whether substances were used during this pregnancy by selecting “Yes”, “No”, or “Unknown”.
- If “Yes”, indicate for each substance select whether the substance was
  - “Used and injected” if there is evidence that the birthing person used the substance during this pregnancy and the substance was injected,
  - “Used and did not inject” if there is evidence that the birthing person used the substance during this pregnancy but the substance was not injected,
  - “Used and unknown if injected” if there is evidence that the birthing person used the substance during this pregnancy but there was no evidence to determine whether the substance was injected,
  - “Did not use” if there is evidence that the birthing person did not use that particular substance during this pregnancy,
  - “Unknown if used” if there is not sufficient evidence to determine whether the birthing person used the particular substance during this pregnancy.
  - Leave blank if you did not search for whether specific substances were used during this pregnancy.
  - The drugs listed here are in alphabetical order and may be checked if there is evidence of a toxicology screen or a notation in records not based on a toxicology screen (e.g., patient self-report).
- Heroin is a semisynthetic narcotic and opiate and should be listed as heroin, opiate, or opioid on the urine toxicology laboratory results sheet.
- Marijuana may be listed on the urine toxicology results as cannabis, a cannabinoid, THC or simply marijuana.
- Methadone is a synthetic narcotic and should be listed as methadone. Any methadone use, whether legal or illegal, should be included as “Yes” to this question.
- If “Other”, specify the name of the substance(s) used.

11.16 WAS A TOXICOLOGY SCREEN DONE ON THE BIRTHING PERSON (EITHER DURING PREGNANCY OR AT THE TIME OF DELIVERY) (**Recommended**, applies to health department & health care providers).

- Select “Yes” if a screen was conducted on the birthing pregnancy during this pregnancy or at the time of delivery. The toxicology testing must have been completed during pregnancy, not before pregnancy. Toxicology screens are usually done using urine or serum.
  - For each substance, select “Not screened” if there’s evidence that the substance was not included in the toxicology screen. If the substance was screened, enter the date of the toxicology screen in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011). Select “Positive” if there was a positive test result for the substance. Select “Negative” if there was a negative test result for the substance. Select “Unknown” if a search for the test result for the substance was documented but the result could not be determined.
  - If screening was for a substance other than those listed, select “Other” and specify the drug metabolites in the space provided.
  - If a screening for the same substance was done on more than one occasion, record additional dates and results in the Comments section. In eHARS, enter the additional screening information on the PCRf on the “Birthing Person History” tab.
  - Heroin is a semisynthetic narcotic and opiate and should be listed as heroin, opiate, or opioid on the urine toxicology laboratory results sheet.
  - Marijuana may be listed on the urine toxicology results as cannabis, a cannabinoid,



- THC or simply marijuana.
- Methadone is a totally synthetic narcotic and should be listed as methadone. Any methadone use, whether legal or illegal, should be included as “Yes” to this question.
- Check “No” if it is known that a screen was not conducted.
- Select “Unknown” after unsuccessful search for this datum.

## 12. Treatment/Services Referrals

### XII. Treatment/Services Referrals (record all dates as mm/dd/yyyy)

Has this child ever taken any ARVs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown									
ARV medication	Reason for use						Date began	Date of last use	
	HIV Tx	PrEP	PEP	PMTCT	HBV Tx	Other (specify reason)			
i. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
ii. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
iii. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
iv. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
v. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> _____	___/___/___	___/___/___	
(Record additional ARV medications in Comments)									
Has this child ever taken PCP prophylaxis <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown    Date began ___/___/___    Date of last use ___/___/___									
This child's primary caretaker is <input type="checkbox"/> 1-Biological parent <input type="checkbox"/> 2-Other relative <input type="checkbox"/> 3-Foster/Adoptive parent, relative <input type="checkbox"/> 4-Foster/Adoptive parent, unrelated <input type="checkbox"/> 7-Social service agency <input type="checkbox"/> 8-Other (specify in comments) <input type="checkbox"/> 9-Unknown									

- Enter the data below for all children reported as perinatally exposed with or without consequent HIV infection; the field “Has this child ever taken PCP prophylaxis” and the associated date field need to be completed only if the child is HIV infected.
- 12.1 HAS THIS CHILD EVER TAKEN ANY ARVS (**Required**, applies to health department & health care providers)
- This variable indicates whether the patient has ever taken any antiretroviral medication. “Yes” indicates there is evidence that the patient has taken ARVs, including self-report.
  - If “Yes”, it is important to enter the dates when use began and, if appropriate, ended. Enter date in *mm/dd/yyyy* format using “..” for unknown values (e.g., 03../2011).
  - “No” indicates there is evidence that the patient has never taken ARVs.
  - “Unknown” should be used when the person completing the form does not know whether or not the patient has ever taken ARVs, after searching for the information or asking the patient.
  - Leave the field blank if there was no attempt to find the information.
- 12.2 ARV MEDICATION (**Recommended**, applies to health department & health care providers)
- List the medications taken.
  - This variable is used to verify that the medication taken was actually an antiretroviral.
  - Enter “unspecified” if an ARV was taken but the name is not known.
  - Refer to [Appendix 12.2](#) for further guidance.
- 12.3 REASON FOR ARV USE (**Required**, applies to health department & health care providers)
- Select reason that applies for each specific ARV medication.
  - “HIV Tx” indicates that the patient used the ARV medication to treat HIV infection.
  - “PrEP” indicates that the patient used the ARV medication prior to HIV diagnosis for HIV preexposure prophylaxis (PrEP). If “PrEP” is selected, please refer to the updated clinical practice guideline for PrEP at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. For surveillance activities, additional follow up with health care providers may be required for certain test results for final determination of HIV status. Federal Drug Administration (FDA) intended usage of ARV medications for PrEP is for persons who weigh at least 35 kg and are sexually active or inject drugs.

- “PEP” indicates that the patient used the ARV medication as postexposure prophylaxis (PEP).
  - “PMTCT” indicates that the patient used the ARV medication to prevent HIV birthing person-to-child-transmission.
  - “HBV Tx” indicates that the patient used the ARV medication to treat hepatitis B virus infection.
  - “Other” indicates that the patients used the ARV medication for a reason other than those indicated above.
- 12.4 DATE BEGAN (**Required**, applies to health department & health care providers)
- For each ARV medication indicated in 12.2, enter the earliest date that the patient took the ARVs, even if ARV use was sporadic.
  - If the first time ARVs were taken occurred after HIV diagnosis, it is very important to enter a date, even an estimated date, later than the date of HIV diagnosis.
  - Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 12.5 DATE OF LAST USE (**Required**, applies to health department & health care providers)
- For each ARV medication indicated in 12.2, enter the most recent date of ARV use.
  - For patients currently on ARVs, record the date of the most recent prescription or known usage. If the information was collected during a patient interview, the date would be the interview date. If the information was collected as part of a medical record review, record the date of the most recent prescription or date of the most recent physician’s note.
  - Enter date in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
- 12.6 HAS THIS CHILD EVER TAKE PCP PROPHYLAXIS? (**Optional**, applies to health department & health care providers)
- If nothing in the medical chart indicates the use of any of these drugs or refers to the prophylactic treatment of PCP, then select “No”.
  - If “Yes”, enter the date the child was started on therapy to prevent the occurrence of PCP and the date of last use in *mm/dd/yyyy* format using “.” for unknown values (e.g., 03/./2011).
  - “Unknown” is used if treatment information in the medical chart is unclear or was unavailable.
  - Refer to [Appendix 12.6](#) for further guidance.
- 12.7 THIS CHILD’S PRIMARY CARETAKER IS (**Optional**, applies to health department & health care providers)
- Select the person who provides the majority of care for the child.
  - Refer to [Appendix 12.7](#) for further guidance.

### 13. Comments (Optional, applies to health department & health care providers)

#### XIII. Comments


- This section can be used for information not requested on the form or for information requested but where there might not be room in the space provided.
- As appropriate, information collected in this section can be entered in existing fields on the PCRF of eHARS.
- Information entered into the “Comments” tab on the PCRF of eHARS will not be transmitted to CDC.

## 14. Local/Optional Fields (Optional, applies to health department)

### XIV. \*Local/Optional Fields


- This section is for collection of data that are not on the form at the state and local level.
- This information is not sent to CDC.

# Appendix. Pediatric HIV Confidential Case Report Form (CDC 50.42B)

## Instructions for Completion

### Purpose

- Information captured on the Pediatric HIV Confidential Case Report Form (PCRf) provides population-based data on diagnostic testing and initiation of prophylaxis and treatment, as well as HIV-related morbidity and mortality among children (*CARE Amendments [Section 2626]*) to support states with prevention activities.
- CDC's Division of HIV Prevention (DHP) needs initial reports and updates to reflect the earliest dates that children meet each reporting criteria (i.e., perinatal exposure, HIV infection, stage 3 or AIDS, seroreverter), as well as changes in diagnostic or vital status.
- When a child who was previously reported as HIV infected has progressed to stage 3 (AIDS) or has died, state/reporting area personnel update the National HIV Surveillance System (NHSS) accordingly.
- After programs receive initial reports of evidence of HIV exposure or infection among children, surveillance staff follow up to determine whether diagnostic status of the child changes. For example, staff update reports of children with perinatal exposure after 6 months of age to confirm or refute HIV infection and again at 18 months of age.
- The PCRf can accommodate updated information including immunologic markers and diagnoses of opportunistic infections.
- Prior to 2023, CDC provided a separate *Perinatal HIV Exposure Reporting* (PHER) form to facilitate collection of additional standardized data on HIV-exposed children. CDC revised the PCRf to include some additional standardized data on HIV-exposed children and retired the separate PHER form in 2023.
- CDC updated the PCRf and related software in 2000 to evaluate the implementation and impact of the Public Health Service (PHS) recommendations on the prevention of transmission of HIV from birthing person to child; accommodate surveillance requirements of the Ryan White CARE Act Amendments of 1996; and accommodate the revised 2000 HIV case definition for perinatal HIV exposure, pediatric infection, and those perinatally exposed but not infected with HIV.
- In 1995, CDC added variables on receipt of maternal ARVs during pregnancy and labor/delivery and neonatal ARV.
- Maternal HIV counseling and testing, prenatal care, and refusal of ARV treatment were added in 1996.
- Viral load tests, receipt of additional antiretroviral (ARV) therapy during labor/delivery for the newborn and elective cesarean were added to the pediatric reporting form in 1999.
- These additions enable reporting areas to identify possible reasons for failures in preventing HIV transmission related to childbirth (i.e., receipt of maternal HIV testing, prenatal care, and antiretroviral treatment).
- As states move toward pediatric HIV exposure reporting, information on receipt of prenatal, intrapartum, and neonatal ARV and receipt of other antiretroviral therapy can be collected for all children born to HIV-infected persons. Timely follow-up of these children to determine infection status will aid in evaluating the impact of these recommendations most effectively.
- For evolution of the pediatric case definition, please refer to the 1987 pediatric AIDS case definition (*MMWR* 1987;36(suppl):1–15S), the 1994 revised classification system for HIV infection in children less than 13 years of age (*MMWR* 1994;43:(No. RR-12):1–10), and the 2000 HIV case definition in the CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus

Infection and Acquired Immunodeficiency Syndrome (*MMWR* 1999;48(RR-13):1–31), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm>, the 2008 case definition (*MMWR* 2008; 57 (RR-10) 1-12 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm>, and the Revised Surveillance Case Definition for HIV Infection — United States, 2014 (*MMWR* 2014;63 (RR03);1-10 at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s\\_cid=rr6303a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_e).

## Pediatric Cases of Public Health Importance (COPHI)

- Reporting area staff should continue to discuss certain priority cases directly with CDC surveillance staff. These include HIV infection in a health care setting, HIV-2 infection, HIV infection attributed to tissue or organ transplantation, suspected transmission due to sexual contact, transmission from the birthing person to the infant due to breast feeding or pre-mastication of food, transfusions after March 1985, or any other unusual transmission circumstances. This direct communication will ensure the timeliest technical support. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.

## 4. Patient Demographics

### 4.1 DIAGNOSTIC STATUS AT REPORT

#### 4.1.1 PERINATAL HIV EXPOSURE

- Although all children aged less than 18 months born to an HIV-infected person were perinatally exposed to HIV, the “Perinatal HIV Exposure” category on the case report form is composed of those with an undetermined HIV infection status.
- A child aged less than 18 months born to an HIV-infected person will be categorized as “Perinatal HIV Exposure” if the child does not meet the criteria for HIV infection or the criteria for presumptively or definitely uninfected.

#### 4.1.2 PEDIATRIC HIV

- Among children <18 months old whose birthing persons were not infected and all children aged ≥18 months, a reportable case of HIV infection must meet at least one of the following criteria:

#### **1.1: Persons Aged ≥18 Months and Children Aged <18 Months whose Birthing Persons were Not Infected**

##### ***1.1.1: Laboratory Evidence***

Laboratory criteria require reporting of the date of the specimen collection for positive test results in multitest algorithms or stand-alone virologic tests and enough information about the tests to determine that they meet any of the following criteria:

- A multitest algorithm consisting of
  - A positive (reactive) result from an initial HIV antibody or combination antigen/antibody test, and
  - An accompanying or subsequent positive result from a supplemental HIV test different from the initial test.

The initial HIV antibody or antigen/antibody test and the supplemental HIV test that is used to verify the result from the initial test can be of any type used as an aid to diagnose HIV infection. For surveillance purposes, supplemental tests can include some not approved by the Food and Drug Administration (FDA) for diagnosis (e.g., HIV-1 viral load test, HIV-2 western blot/immunoblot antibody test, and HIV-2 NAT). However, the initial and supplemental tests must be "orthogonal" (i.e., have different antigenic

constituents or use different principles) to minimize the possibility of concurrent nonspecific reactivity. Because the antigenic constituents and test principles are proprietary information that might not be publicly available for some tests, tests will be assumed to be orthogonal if they are of different types. For example:

- One test is a combination antigen/antibody test and the other an antibody-only test.
- One test is an antibody test and the other a NAT.
- One test is a rapid immunoassay (a single-use analytical device that produces results in <30 minutes) and the other a conventional immunoassay.
- One test is able to differentiate between HIV-1 and HIV-2 antibodies and the other is not.

Tests also will be assumed to be orthogonal if they are of the same type (e.g., two conventional immunoassays) but made by different manufacturers. The type of HIV antibody test that verifies the initial test might be one formerly used only as an initial test (e.g., conventional or rapid immunoassay, HIV-1/2 type-differentiating immunoassay), or it might be one traditionally used as a supplemental test for confirmation (e.g., western blot, immunofluorescence assay).

- A positive result of a multitest HIV antibody algorithm from which only the final result was reported, including a single positive result on a test used only as a supplemental test (e.g., HIV western blot, immunofluorescence assay) or on a test that might be used as either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (e.g., because the algorithm customarily used by the reporting laboratory is known).
- A positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., non-antibody) tests:
  - Qualitative HIV NAT (DNA or RNA)
  - Quantitative HIV NAT (viral load assay)
  - HIV-1 p24 antigen test
  - HIV isolation (viral culture) or
  - HIV nucleotide sequence (genotype).

#### ***1.1.2: Clinical (Non-Laboratory) Evidence***

Clinical criteria for a confirmed case (i.e., a "physician-documented" diagnosis for which the surveillance staff have not found sufficient laboratory evidence described above) are met by the combination of:

- A note in a medical record by a physician or other qualified medical-care provider that states that the patient has HIV infection, and
- One or both of the following:
  - The laboratory criteria for a case were met based on tests done after the physician's note was written (validating the note retrospectively).
  - Presumptive evidence of HIV infection (e.g., receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained

- Among children aged less than 18 months whose birthing persons have an unknown infection status or were known to be infected a reportable case of HIV infection must meet at least one of the following criteria:

**1.2: Children Aged <18 Months Born to Birthing Persons Who Have an Unknown Infection Status or were Known to be Infected**

**1.2.1: Laboratory Evidence**

A child aged <18 months is categorized for surveillance purposes as HIV infected if all of the following criteria are met:

- Positive results on at least one specimen (not including cord blood) from any of following HIV virologic tests:
  - HIV-1 NAT (DNA or RNA)
  - HIV-1 p24 antigen test, including neutralization assay for a child aged >1 month
  - HIV isolation (viral culture) or
  - HIV nucleotide sequence (genotype).
- The test date (at least the month and year) is known.
- One or both of the following:
  - Confirmation of the first positive result by another positive result on one of the above virologic tests from a specimen obtained on a different date or
  - Both of the following:
    - No subsequent negative result on an HIV antibody test, and no subsequent negative result on an HIV NAT before age 18 months.

**1.2.2: Clinical Evidence**

- The same criteria as for section 1.1.2 above (1.1.2 Clinical [Non-Laboratory] Evidence for Persons Aged ≥18 Months and Children Aged <18 Months whose Birthing Persons were Not Infected) or
- All three of the following alternative criteria:
  - Evidence of perinatal exposure to HIV infection before 18 months of age:
    - A birthing person with documented HIV infection or
    - A confirmed positive test for HIV antibody (e.g., a positive initial antibody test confirmed by a supplemental antibody test) and a birthing person whose infection status is unknown or undocumented.
  - Diagnosis of a stage-3-indicative opportunistic illness.
  - No subsequent negative result on an HIV antibody test.

4.1.3 PEDIATRIC AIDS

- Children who are HIV infected and exhibit any of the following stage 3 (AIDS)-defining clinical conditions should be reported as stage 3 (AIDS) cases; although most of these conditions appear among adult stage 3 (AIDS) diagnostic criteria, asterisked conditions apply only to aged <6 years, and conditions with a dagger

footnote symbol apply only to children aged  $\geq 6$  years and adults.

- Bacterial infections, multiple or recurrent\*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive†
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal ( $>1$  month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age  $>1$  month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcer(s) ( $>1$  month's duration); or bronchitis, pneumonitis, or esophagitis (onset at age  $>1$  month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal ( $>1$  month's duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- *Mycobacterium avium* complex or *M. kansasii*, disseminated or extrapulmonary
- *Mycobacterium tuberculosis* of any site, pulmonary†, disseminated, or extrapulmonary
- *Mycobacterium*, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jirovecii* (previously known as "*Pneumocystis carinii*") pneumonia
- Pneumonia, recurrent†
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of brain, onset at age  $>1$  month
- Wasting syndrome due to HIV

† Only among adults and children aged  $\geq 6$  years.

\* Only among children aged  $<6$  years.



#### 4.1.4 PEDIATRIC SEROREVERTER

- Virtually all children less than 18 months of age born to HIV-infected persons are antibody positive at birth.
- A child aged < 18 months born to an HIV-infected person will be categorized for surveillance purposes as “not infected with HIV” if the child does not meet the criteria for HIV infection but meets the following criteria:

##### **3.1: Uninfected**

A child aged <18 months who was born to an HIV-infected person or had a positive HIV antibody test result is classified for surveillance purposes as not infected with HIV if all three of the following criteria are met:

- Laboratory criteria for HIV infection are not met (see section 1.2.1)
- No diagnosis of a stage-3-defining opportunistic illness attributed to HIV infection and
- Either laboratory or clinical evidence as described below.

##### **3.1.1: Laboratory Evidence**

###### *Definitively Uninfected*

- No positive HIV NAT (RNA or DNA) and
- At least one of the following two criteria:
  - At least two negative HIV NATs from specimens obtained on different dates, both of which were at age  $\geq 1$  month and one of which was at age  $\geq 4$  months.
  - At least two negative HIV antibody tests from specimens obtained on different dates at age  $\geq 6$  months.

###### *Presumptively Uninfected*

- Criteria for definitively uninfected with HIV are not met
- At least one of the following four laboratory criteria are met:
  - At least two negative NATs from specimens obtained on different dates, both of which were at age  $\geq 2$  weeks and one of which was at age  $\geq 4$  weeks.
  - One negative NAT (RNA or DNA) from a specimen obtained at age  $\geq 8$  weeks.
  - One negative HIV antibody test from a specimen obtained at age  $\geq 6$  months.
  - If criteria for HIV infection had initially been met by one positive HIV NAT test then it must have been followed by at least two negative test results from specimens obtained on different dates, one of which is:
    - A NAT test from a specimen obtained at age  $\geq 8$  weeks, or
    - An HIV antibody test from a specimen obtained at age  $\geq 6$  months.
- No subsequent positive NAT

##### **3.1.2: Clinical Evidence**

A note in a medical record by a physician or other qualified medical-care provider states that the patient is not infected with HIV.

## **5. Residence at Diagnosis**

- For reports of perinatal HIV exposure, enter the patient’s city, county, state/country, and ZIP code of residence at the time when HIV infection was first considered, either clinically or through laboratory evaluation.

- For HIV, stage 0, 1, 2, and unknown case reports, enter residence at the date of HIV infection diagnosis. The date of diagnosis of HIV infection is the earliest date on which the surveillance case definition for HIV infection, any stage, was satisfied in accordance with laboratory and clinical criteria (see the Revised Surveillance Case Definition for HIV Infection at <http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf>).
- If a test result is not available, enter patient's residence at the date of *physician diagnosis* of HIV infection.
- If the patient's residence changes between diagnosis of perinatal HIV exposure and confirmed HIV infection, record new address.
- If laboratory slips are not available, enter the patient's residence at the date of *physician diagnosis* of HIV infection. For HIV, stage 3 (AIDS) case reports, enter patient's residence at the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.
- For further guidance about residency assignment, see Technical Guidance File *Date and Place of Residence*.

## 6. Facility of Diagnosis

### 6.2 FACILITY NAME

- For reports of perinatal HIV exposure, enter the name of the facility where child was first evaluated for HIV infection, either clinically or through laboratory evaluation.
- The hospital where the birthing person obtained prenatal care should not be used to answer this question unless it was also the facility where the child was born and HIV infection was considered as a diagnosis at the time of the child's birth or at the time of subsequent physician/clinic visits.
- For reports of confirmed HIV infection, enter the name of the facility associated with the date of HIV infection diagnosis. The date of diagnosis of HIV infection is the earliest date on which the surveillance case definition for HIV infection, any stage, was satisfied in accordance with laboratory and clinical criteria (see the Revised Surveillance Case Definition for HIV Infection at <http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf>).
- If test results were not in the medical record, enter the name of the facility where the child's HIV infection was diagnosed and documented by the health care provider. Enter facility uniformly to prevent the occurrence of multiple names for a given facility.
- For HIV, stage 3 (AIDS) case reports, enter the name of the facility associated with the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.
- These fields strictly apply to facility where HIV or HIV infection stage 3 (AIDS) was diagnosed. Where chart abstraction is conducted at a facility other than the Facility of Diagnosis document report source in the document source field in the II. Health Department Use Only section of the case report form and in III. Facility Providing Information section of the case report form, as applicable.

## 7. Patient History

- This information is often found in the birthing person's chart in the discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact the child's provider about birthing person and child risk factor information.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection. This information can be difficult to find, particularly if the patient has not been interviewed. States should have risk factor ascertainment procedures tailored to their jurisdictions.

## 7.1 BIRTHING PERSON'S HIV INFECTION STATUS

- “Refused HIV testing” should be selected if birthing person’s refusal is documented in the medical chart.
- If the birthing person has been tested for HIV and found to be uninfected at or after the child’s birth, then perinatal transmission is not the presumed mode of exposure to HIV infection.
- If birthing person-to-infant transmission through breast-feeding is considered to be the only mode of transmission, please alert the state or local NIR coordinator.
- If dates are not available, please review medical charts to determine when HIV diagnosis for the birthing person occurred in relationship to the child’s birth and select:  
Known HIV+ before pregnancy;  
Known HIV+ during pregnancy;  
Known HIV+ sometime before birth;  
Known HIV+ at delivery;  
Known HIV+ after child’s birth; or  
HIV+, time of diagnosis unknown.
- If no information is available regarding HIV status for the birthing person, please select:  
HIV status unknown.

## 10. Birth History (for patients exposed perinatally with or without consequent infection)

### 10.4 BIRTH HISTORY

#### 10.4.6 CONGENITAL DISORDERS

- Data collected will be used to evaluate changes in incidence or other unusual patterns of serious birth defects among children exposed to zidovudine in utero compared with those who were not exposed and with the general population.
- Approximately 3%–4% of all babies will have serious birth defects (e.g., neural tube defects, congenital heart defects, esophageal atresia, and cleft lip/palate).
- The methods and definitions used were developed by the CDC National Center on Birth Defects and Developmental Disabilities and are currently used in the Metropolitan Atlanta Congenital Defects Program, an active surveillance system for birth defects in the Atlanta metropolitan area.
- Select “Yes” if the child meets the case definition for birth defects as defined by the CDC National Center on Birth Defects and Developmental Disabilities as listed below.
- Criteria for Inclusion as Reportable Birth Defect:
  - The child must have a structural or genetic birth defect or other specified birth outcome that can adversely affect his or her health and development;
  - The structural or genetic birth defect must be diagnosed or its signs or symptoms recognized within the first year of life;
  - The infant must have a gestational age of at least 20 weeks or a birth weight of at least 500 grams; and
  - A case must be abstracted by the child’s sixth birthday.
- Criteria for Exclusion:
  - Defects such as normal variants or minor anomalies are considered excludable. Diagnoses that may be normal variants or minor anomalies may be included only if associated with another reportable defect.
  - Imprecise diagnoses (probable, possible, compatible with, consistent with, suspected, questionable, suggestive of, etc.) should be abstracted and coded as such and follow-up conducted to ascertain true status.
  - For children with possible birth defects, please review newborn and

hospital records including the face sheet; history and physical; discharge summary; operative, laboratory, x-ray, cardiac catheterization, and autopsy reports; and notes and consultations by physicians, nurses, and social and psychological services.

- In addition, birth defect (i.e., congenital anomalies) information is also collected on the standard US birth certificate.
  - Hospital records should be reviewed to determine if a reportable defect is present. Each reportable condition is coded separately according to the birth defect code (see below). These codes are based on ICD-9 or ICD-10 codes but provide more specific diagnostic information.
  - If reportable birth defects are diagnosed, select “Yes” and abstract all diagnoses onto the case report form.
  - Include discrepant diagnoses. Also include diagnoses appearing in the chart that have not been ruled out by an expert or laboratory test.
  - If the infant is diagnosed with a syndrome, record the name and code of the syndrome as well as the individual defects.
  - If there is a question about whether a diagnosis is reportable or how to code any diagnosis, please contact the CDC HIV Surveillance Branch surveillance project officer assigned to the state/local HIV surveillance program.
- BIRTH DEFECTS CODE
    - The 6-digit defect codes (<https://www.cdc.gov/ncbddd/birthdefects/macdp.html>) are based on 3- to 5-digit ICD-9-CM or ICD-10-CM codes from a birth certificate or medical records (or ICD-9 or ICD-10 codes from death certificates). The shorter codes may be used in place of the 6-digit codes. Enter the code for the birth defect given in the birth certificate, medical record, or death certificate. If the code is not available in those places, but the birth defect is described using medical terminology, then look up the corresponding code in the ICD-9-CM-based list (downloadable from <http://www.cdc.gov/ncbddd/birthdefects/macdp.html>) if the record was from before October 1, 2014, or in the ICD-10-CM-based list (downloadable from <http://www.cdc.gov/nchs/icd/icd10cm.htm>) if the record was from October 1, 2014 or later.
    - If defects exist, list all on the case report form and enter in the Comments section. In eHARS, if there are more than five congenital defects then enter the information on the additional congenital defects on a separate PCRF document.

## 11. Birthing Person History

### 11.13 WAS THE BIRTHING PERSON SCREENED FOR ANY OF THE FOLLOWING CONDITIONS DURING THIS PREGNANCY

- GROUP B STREP (GBS) - Group B streptococci. A major cause of perinatal bacterial infections and systemic and focal infections in infants. Invasive disease categorized into early onset (1<sup>st</sup> week of life) and late onset (usually at 3-4 weeks of life). Colonization late in pregnant persons and newborns ranges from 5% to 35%. Intrapartum chemoprophylaxis is IV Penicillin G. Two types of prevention strategies may be used:
  - Screening all pregnant persons at 35 to 37 weeks for vaginal and rectal GBS colonization and offering intrapartum chemoprophylaxis to those identified as GBS carriers; or

- Risk factor-based strategy - prophylaxis given to persons with intrapartum risk factors including gestation < 37 weeks, ≥ 18 hours since rupture of membrane, or temperature of 38° C or greater.
  - HEPATITIS B (Hepatitis B surface antigen, HBsAg) - Detects acutely or chronically infected persons. Prenatal HbsAg screening of all pregnant persons is recommended. Babies of birthing persons who are HbsAg (+) must have HBIG and HBV vaccine within 12 hours of birth to prevent perinatal HBV infection. Be sure the test result is for the surface antigen rather than the antibody (anti-HBs), core antigen (HbcAg), or antibody (anti-HBc); or Hepatitis B e antigen (HbeAg) or antibody (anti-HBe). This test is usually done at the initial prenatal visit or at the time of labor and delivery for persons with risk factors for hepatitis B infection and persons whose status is unknown.
  - RUBELLA - Screening is usually done at the initial prenatal visit. If ‘negative’ the birthing person should be immunized.
  - SYPHILIS - All pregnant persons should receive serologic screening for syphilis early in pregnancy with a nontreponemal test (e.g., VDRL and RPR). In addition, screening is recommended in the third trimester for those in high prevalence areas or for persons with risk factors for syphilis infection. Nontreponemal antibody tests are used for screening purposes and presumptive diagnosis: VDRL (venereal disease research laboratory); RPR (rapid plasma reagin test; STS serologic test for syphilis, syphilis screening test); ART (automated reagin test). The nontreponemal antibody test should be confirmed with a treponemal antibody test (e.g., FTA-ABS, MHA-TP). If a pregnant person has a reactive nontreponemal test and a persistently negative treponemal test, a false positive test is inferred. (Reference: Red Book 2021- American Academy of Pediatrics).
- 11.14 WERE ANY OF THE FOLLOWING CONDITIONS DIAGNOSED FOR THE BIRTHING PERSON DURING THIS PREGNANCY OR AT THE TIME OF LABOR AND DELIVERY
- BACTERIAL VAGINOSIS - Clinician diagnosis of bacterial vaginosis. Sometimes abbreviated BV.
  - CHLAMYDIA (*Chlamydia trachomatis*) - Record positive test for chlamydia (a positive culture, positive EIA, or detection of chlamydial antigen or nucleic acid).
    - Name of laboratory tests - *Chlamydia* cell culture (TRIC Agent Culture); direct fluorescent antibody (DFA) tests; enzyme immunoassay (EIA) tests; nucleic acid hybridization (DNA probe) tests; and PCR and LCR.
  - GENITAL HERPES - Active (herpes genitalis) - Primary herpes (first episode of herpes) or recurrence of herpes during pregnancy or at labor and delivery.
    - Name of laboratory tests - herpes virus culture; herpes cytology (herpetic inclusion bodies, cytology, inclusion body stain, Tzanck smear, Giemsa stain viral study); rapid diagnostic tests- direct immunofluorescent AB or EIA; HSV Ag; or polymerase chain reaction (PCR).
  - GONORRHEA (*Neisseria gonorrhea*) - Record if culture positive.
    - Name of laboratory tests - *Neisseria gonorrhea* culture (GC Culture, Gonorrhea Culture); Thayer-Martin medium; chocolate agar; detection of nucleic acid.

- **GROUP B STREP** - Group B streptococci. A major cause of perinatal bacterial infections and systemic and focal infections in infants. Invasive disease categorized as early onset (1<sup>st</sup> week of life) and late onset (usually at 3-4 weeks of life). Colonization late in pregnant persons and newborns ranges from 5% to 35%. Intrapartum chemoprophylaxis is IV Penicillin G. Two types of prevention strategies may be used:
  - Screening all pregnant persons at 35 to 37 weeks for vaginal & rectal GBS colonization, offering intrapartum chemoprophylaxis to those identified as GBS carriers; or
  - Risk factor-based strategy in which prophylaxis is given to persons with intrapartum risk factors: gestation < 37 weeks, ≥ 18 hours since rupture of membrane, or temperature 38° C or greater.
- **HEPATITIS B** (Hepatitis B surface antigen, HbsAg) - Detects acutely or chronically infected persons. Prenatal HbsAg screening of all pregnant persons is recommended. Babies of birthing persons who are HbsAg (+) must have HBIG & HBV vaccine within 12 hours of birth to prevent perinatal HBV infection.
  - Be sure the test result is for the surface antigen rather than the antibody (anti-HBs), core antigen (HbcAg) or antibody (anti-HBc); or Hepatitis B e antigen (HbeAg) or antibody (anti-HBe). Tests are usually done at the initial prenatal visit or at the time of labor and delivery for persons with risk factors of hepatitis B infection and persons whose status is unknown.
- **HEPATITIS C** - Tests do not distinguish between acute, chronic, or resolved infection. Diagnosis by antibody assays involves initial screening EIA. Repeatedly positive results are confirmed by a recombinant immunoblot assay (RIBA). Highly sensitive PCR assays for detection of HCV RNA are also available.
  - Name of laboratory test - EIA (Enzyme immunoassay) screen, confirmed by recombinant immunoblot assay (RIBA).
- **PELVIC INFLAMMATORY DISEASE (PID)** - Look for documentation of a clinical diagnosis of PID. A note stating 'rule out PID' does not indicate the person had PID.
- **SYPHILIS** (*Treponema pallidum*) - All pregnant persons should receive a serologic screen for syphilis early in pregnancy with a nontreponemal test (e.g., VDRL, RPR, STS, and ART) and preferably again at delivery. In addition, screening is recommended in the third trimester for those in high prevalence areas or those at high risk.
  - Nontreponemal antibody tests are used for screening. Any reactive nontreponemal test must be confirmed by a specific treponemal test (FTA-ABS and MHA-TP) to exclude false positive results which can be caused by a viral infection (e.g., infectious mononucleosis, hepatitis, varicella and measles), lymphoma, TB, malaria, endocarditis, connective tissue disease, pregnancy, or abuse of injection drugs. If a pregnant person has a reactive nontreponemal test and a persistently negative treponemal test, a false positive test is inferred. A positive FTA-ABS or MHA-TP usually remains reactive for life, even after successful therapy. Also, look for evidence of treatment for syphilis - receipt of penicillin (bicillin) 2.4 million units is the standard treatment for syphilis in the birthing person. Check whether the child was diagnosed with or treated for congenital syphilis with penicillin for 10 days. A physician diagnosis will be clearly documented in the infant's birth chart. Also check the congenital syphilis registry to confirm congenital syphilis, with consideration for confidentiality and security of an individual's HIV or stage 3 or AIDS status.

- Name of laboratory tests - *Presumptive* diagnosis: nontreponemal tests (for screening purposes) VDRL (venereal disease research laboratory); RPR (rapid plasma reagin test, serologic test for syphilis, STS, syphilis screening test, ART-automated reagin test). *Definitive* diagnosis: treponemal tests (for diagnostic purposes) Darkfield examination (Darkfield microscopy, syphilis; *Treponema Pallidum* Darkfield examination); FTA-ABS (Fluorescent Treponemal Antibody Absorbed Test, Fluorescent Treponemal Antibody Adsorption); MHA-TP (Microhemagglutination assay for Antibody to *Treponema Pallidum*; Microhemagglutination, *Treponema Pallidum*.
- TRICHOMONAS (*Trichomonas vaginalis*) - Record clinician diagnosis of trichomonas. Trichomonas is diagnosed by finding trichomonas on a wet mount.
  - Name of laboratory tests - Trichomonas preparation (Hanging Drop Mount for Trichomonas, *Trichomonas vaginalis* wet preparation; Trich Prep; wet preparation for *Trichomonas vaginalis*).

## 12. Treatment/Services Referrals

### 12.2 ARV MEDICATION

- Please refer to the *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection* [https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV\\_GL.pdf](https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV_GL.pdf).

### 12.6 HAS THIS CHILD EVER TAKE PCP PROPHYLAXIS?

- Please refer to *MMWR* 1995;44(RR-4):1–11 for the 1995 Revised Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia (PCP) for Children Infected with or Perinatally Exposed to HIV. Examples of PCP prophylaxis include Trimethoprim/sulfamethoxazole (TMP/SMX, Bactrim, Septra), Pentamidine, and Dapsone.
- TMP/SMX (Bactrim, Septra) can be used to treat infections other than HIV but is usually used for a shorter period. For example, TMP/SMX is used for 2–3 weeks to treat otitis media and would NOT be recorded as “Yes” in this field.
- Include as PCP prophylaxis if it is clearly noted as such in the medical chart or given for a period of 2 weeks or longer.

### 12.7 THIS CHILD’S PRIMARY CARETAKER IS

- “Other relative” refers to children living with an aunt, grandmother, etc. in an informal arrangement, and the relative does not receive a stipend for providing care.
- If a child lives with a relative and that relative is paid a stipend for caring for the child, “Foster/Adoptive parent, relative” should be selected.
- A child is in “foster/adoptive parent, unrelated” if living with someone other than a relative.
- “Adoptive parent, relative” refers to child who has been legally adopted by a relative. This includes children with deceased parents whose legal custody has been transferred to a relative.
- If the adoptive parent is unrelated, please select “foster/adoptive parent, unrelated”. This includes children with deceased parents whose legal custody has been transferred to a person who is unrelated to the child.
- “Social service agency” refers to children whose primary caretaker is a social service agency, which usually refers to children living in group home situations.
- For children being cared for in situations not described above, select “other” and specify in this section.

## **National HIV Surveillance System (NHSS)**

### **Attachment 4(c)**

Technical Guidance for HIV Surveillance Programs: Duplicate Review



# Technical Guidance for HIV Surveillance Programs

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## **Duplicate Review**

HIV Surveillance Branch  
Atlanta, Georgia

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## Background

HIV surveillance systems must provide a reliable measure of the number of persons in need of HIV prevention and care services at the local, state, and national levels. An accurate HIV surveillance system is one that minimizes the degree to which it overcounts or undercounts reported cases of HIV infection and maximizes the reliability with which data for a given person are linked over time. Failing to properly link an incoming surveillance report to an existing case leads to overcounting and incomplete case information or incorrectly linking an incoming surveillance report to an existing case may lead to undercounting and data contamination.

Because doctors, hospitals, laboratories, and other reporting entities may be required to report all diagnoses of HIV infection, duplicate case reports within a state (intrastate) or between states (interstate) may not be identified during routine case entry into the surveillance database. To prevent overcounting and undercounting of cases, identification of potential intrastate and interstate duplicate case reports, merging case reports that have been deemed to be duplicates at all levels, and providing duplicate review resolution to CDC (i.e., Same as or Different than) must be carried out on a regular basis.

Within a state, surveillance software and routine surveillance practices are used to identify and eliminate duplicate case reports. These processes can use personally identifiable information (PII) and other useful information maintained at a state or local level. At the national level, CDC does not receive PII (e.g., name, Social Security Number) so duplicate case reports cannot be identified with the same degree of accuracy. Thus, CDC requires all surveillance areas to perform both intrastate and interstate review and de-duplication on a routine basis and ensure that each person in the surveillance database is given one unique state-assigned case number (stateno).

## Intrastate Duplicate Review

The prerequisites (structural requirements), best practices (process standards), and outcome standards for intrastate duplicate review are described next, followed by more in-depth guidance on specific topics.

### Structural Requirements

1. Case, laboratory, and other reports received on a person
2. HIV Surveillance System Software, eHARS

3. eHARS User Guide<sup>1</sup>
4. eHARS Technical Reference Guide<sup>2</sup>
5. Data processing policies, procedures, and tools for record linkage (see Technical Guidance File *Record Linkage*)
6. Procedures for evaluating accuracy of HIV surveillance systems (see Technical Guidance File *Evaluation and Data Quality*)
7. Variables to ascertain potential intrastate duplicate case reports:
  - The eHARS report “Identify Intrastate Duplicate Cases Based on CDC Matching String” is available under Operational in the eHARS REPORT module index. The report identifies and generates a list of potential duplicate case reports within a jurisdiction’s eHARS using CDC matching strings. Cases are first matched using the following Person View variables: last name soundex (last\_name\_sndx), date of birth (dob), sex at birth (birth\_sex) and state of residence at HIV diagnosis (rsh\_state\_cd). Country of residence at HIV diagnosis (rsh\_country\_cd) is used if rsh\_state\_cd is ‘FC – Foreign Country’. If no match is found, then cases are matched on last name soundex, date of birth, sex at birth and state or country of residence at stage 3 AIDS diagnosis (rsa\_state\_cd / rsa\_country\_cd). Cases that match on the CDC string but have previously been confirmed by the jurisdiction as different persons are excluded from the list.
  - In addition to running the above eHARS report, jurisdictions are encouraged to perform more in-depth duplicate reviews using information that are readily available at the state level, e.g., first name (first\_name), last name (last\_name), middle name (middle\_name), first and last name soundex (first\_name\_sndx, last\_name\_sndx), date of birth (dob), sex at birth (birth\_sex), race/ethnicity (race), full Social Security Number (ssn), death date (dod). When these values are identical, other variables may be used to determine if the cases are duplicates. Examples of such variables include: medical record number (medrecno); inmate identification number (prisno); date of diagnosis of HIV infection (hiv\_dx\_dt); and date of diagnosis of stage 3 AIDS diagnosis (aids\_dx\_dt).

## Process Standards

### 1. Frequency of Procedure

- Monthly run eHARS canned report Identify Intrastate Duplicate Cases Based on CDC Matching String and either merge duplicate case reports that represent the

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<sup>1</sup> All health department HIV Surveillance personnel who are United States citizens are eligible to access the HIV Surveillance Branch (HSB) workspace on CDC SharePoint at <https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx>. If you have questions or problems with access, please contact your assigned CDC epidemiologist or the HIV Surveillance Branch main number at (404) 639-2050.

<sup>2</sup> See footnote 1, immediately above. eHARS technical documentations available in SharePoint.

same person or update the duplicate status in eHARS to “2-Different than” if the case reports represent two different persons.

- Jurisdictions should also perform more in-depth intrastate duplicate review using exact and fuzzy (i.e., inexact) matching methods.

## **2. Records that Represent the Same Person**

- Case reports that have been confirmed to be duplicates should be merged. When merging, retain the STATENO belonging to the case that was first entered into eHARS (the case with the earlier Person View enter\_dt).
- eHARS contains a Transfer Document feature which can be found under Document and Case Maintenance in the ADMIN module index. Transfer Document allows the user to merge duplicate case reports by entering the appropriate state and state-assigned case number (stateno), eHARS unique identifier (ehars\_uid) or document unique identifier (document\_uid) of the source case (i.e., the case with the later Person View enter\_dt), and the appropriate state and state-assigned case number (stateno) or eHARS unique identifier (ehars\_uid) of the target case (i.e., the case with the earlier Person View enter\_dt).
- The Adult Case Report Form (ACRF) and the Pediatric Case Report Form (PCRF) documents in eHARS contain a Duplicate Review tab that allows the user to enter duplicate status information regarding two reported cases of HIV infection. An example is when a person was a pediatric “Seroreverter” and was later infected with HIV (see Technical Guidance File *Pediatric HIV Confidential Case Report Form and Perinatal HIV Exposure Reporting Form*). This person would be given two different state (or city/county) numbers; one associated with the “Seroreverter” and another associated with the HIV infection diagnosis.
  - Jurisdictions may utilize the Duplicate Review tab to maintain a log of cases (e.g., STATENOs) that have been merged with another case within the jurisdiction’s eHARS. To do this, the surveillance staff will need to enter an ACRF or PCRF document for the target case and, under the Duplicate Review tab, select duplicate status as ‘1 – Same as’, select the jurisdiction’s name for site and enter the STATENO of the source case as the state ID number.

## **3. Records that Represent Different Persons**

- When a pair of case reports in the “Identify Intrastate Duplicate Cases Based on CDC Matching String” report has been determined to represent two different persons, the jurisdiction should notify CDC by entering an ACRF or PCRF document into eHARS for at least one of the cases and updating the duplicate status under the Duplicate Review tab to “2 – Different than” and entering the jurisdiction’s name for site and the STATENO of the other case in the pair as the state ID number.

## Outcome Standard

- Of all persons with diagnosed HIV infection who were reported to the local surveillance program through the end of the evaluation year (cumulative), less than or equal to ( $\leq$ ) 1% have duplicate case reports, assessed 12 months after the evaluation year. Duplication rates should be calculated using methods shown in the Technical Guidance File *Evaluation and Data Quality*.

## Interstate Duplicate Review

The same HIV-infected person may be reported multiple times to public health departments in different states. Interstate duplicate case reports can result from persons moving or receiving care in different states over time and being reported to multiple state health departments in accordance with local reporting requirements. Through routine duplicate review, health departments may determine that a potential case may have been previously diagnosed in another jurisdiction rather than a new or late diagnosis reported to their surveillance systems. Further, interstate duplicate review is a critical component of Data-to-Care and other routine surveillance activities (e.g., updating current address, HIV medical care status, viral suppression, and vital status) to ensure persons with HIV infection are tested, diagnosed, linked and retained in care, and virally suppressed.

Interstate duplicate review is also designed to ensure that a case of HIV infection is counted only once in the National HIV Surveillance System (NHSS). The potential for duplicate reporting in the NHSS may increase as persons with HIV infection remain healthier longer due to advances in the clinical treatment of HIV infection and increased laboratory-driven surveillance. Therefore, routine interstate case de-duplication activities are critical to ensure accurate case counts at the national level. In 1986 and 2001, respectively, the Council of State and Territorial Epidemiologists (CSTE) passed resolutions for state-to-state reciprocal notification processes for AIDS and HIV case reporting to encourage resolution of duplicate case counting (See <https://cdn.ymaws.com/www.cste.org/resource/resmgr/PS1/2001-ID-04.pdf>). HIV surveillance program staff should communicate with other states to resolve potential duplicates using guidance outlined below in accordance with CSTE position statements and detailed procedural guidance disseminated by CDC.

Potential interstate duplicate case reports may be identified in three ways. Before entering a new case into eHARS, surveillance staff may use the Secure Online Soundex Match application [accessible 24/7 through CDC's Secure Access Management Services (SAMS) Secure Data eXchange (SDX)] to determine if the case has been reported by another jurisdiction. For access to the Secure Online Soundex Match application, state and local health departments should contact the CDC epidemiologist assigned to your jurisdiction or the CDC Division of HIV Prevention (DHP) Helpdesk at 1-877-659-7725 to complete the Soundex Match application form.

If a potential match is identified by the Secure Online Soundex Match application, the jurisdiction should contact the other reporting jurisdiction to determine if the case report represents the same person or different persons. There are three potential outcomes:

1. The case has been reported by another jurisdiction. In this situation, surveillance staff should still enter the case into eHARS and ensure that the data elements in the Duplicate Review tab are appropriately populated (i.e., if the same person, select '1 – Same as' for 'duplicate status', the name of the other jurisdiction for 'site', and the other jurisdiction's STATENO for the case for 'state ID number')
2. The case has not been reported by another jurisdiction, but the person's last name soundex, date of birth, and sex at birth match those of a case reported by another jurisdiction. In this situation, when entering the case into eHARS, surveillance staff should also ensure that data elements in the Duplicate Review tab are populated (i.e., if different persons, select '2 – Different than' for 'duplicate status', the name of the other jurisdiction for 'site', and the other jurisdiction's STATENO for the case for 'state ID number')
3. The case has not been reported by another jurisdiction and no match on the last name soundex, date of birth, and sex at birth are found by the Secure Online Soundex Match application, then data elements in the Duplicate Review tab should be left blank when entering the case into eHARS.

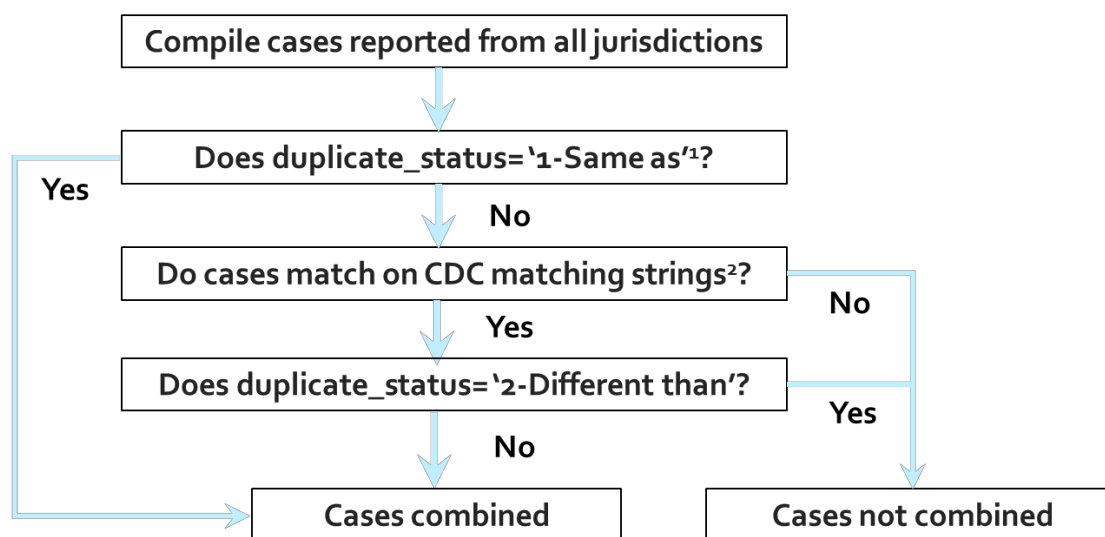
The second way that potential interstate duplicate case reports are identified is through duplicate review reports that CDC distributes to local and state health departments; the semi-annual Routine Interstate Duplicate Review (RIDR) reports and the Cumulative Interstate Duplicate Review (CIDR) report that was distributed in January 2018. RIDR/CIDR reports are generated after data transmitted to CDC by local and state health departments have been consolidated. It is highly encouraged that jurisdictions proactively use the Secure Online Soundex Match application for more timely identification of potential duplicates to help reduce the number of potential interstate duplicate pairs in their semi-annual RIDR reports. When a jurisdiction contacts the other reporting jurisdiction(s) to determine if a case report represents the same person or different persons, the jurisdictions should share any relevant information (e.g., STATENO) to update their case records so that the reports are properly merged later for de-duplication.

The third way that potential interstate duplicate case reports can be identified is using a secure data sharing tool. Through the grant PS18-1805, Georgetown University is funded to provide a secure data sharing tool with matching algorithm to all 59-funded state and local health departments. The secure data sharing tool will assess case pairs using information available at the local level that is not available at the national level (e.g., Social Security Number, last name, etc.), and will generate a report indicating the matching level for each potential duplicate (e.g., exact, extremely high, etc.). Therefore, the tool can more efficiently identify "exact" matches compared to standard RIDR/CIDR methods and may also find matches not detected through RIDR/CIDR. However, accuracy of the matches should be determined before entering the information into eHARS. Accuracy can be determined by selecting a subset of matches at various matching levels and discussing them further with the other jurisdictions to determine if they are true matches. This will establish a threshold where matches can be assumed to be true matches. For details on Georgetown's secure data sharing tool and requirements for participation, please contact Georgetown University at [PS18\\_1805@georgetown.edu](mailto:PS18_1805@georgetown.edu).

## National Data Processing and RIDR/CIDR Report Generation

To prevent overcounting of cases at the national level, on a quarterly basis, CDC de-duplicates the national HIV surveillance database as part of National Data Processing. The de-duplication process involves 1) identifying duplicate case reports and 2) combining duplicate case reports as appropriate for the case (Figure 1). Duplicate case reports are identified using the CDC match strings as well as the eHARS duplicate review data. Cases are first linked by last name soundex (last\_name\_sndx), date of birth (dob), sex at birth (birth\_sex), and state of residence at HIV diagnosis (rsh\_state\_cd). Country of residence at HIV diagnosis (rsh\_country\_cd) is used if rsh\_state\_cd is 'FC – Foreign Country'. If no match is found, the process substitutes state and country of residence at stage 3 AIDS diagnosis (rsa\_state\_cd / rsa\_country\_cd) for state and country of residence at HIV diagnosis. Moreover, case reports are regarded as duplicates if they do not agree on the CDC match strings but one or more jurisdiction's duplicate review data indicate that the cases are the "1 – Same as"; case reports are regarded as for different persons if they match on the CDC match string, but one or more jurisdiction's duplicate review data indicate that the cases are "2 – Different than".

Figure 1: National Duplicate Processing



¹Conflicting duplicate status are ignored during duplicate processing (i.e., Case A says '1 - Same as' Case B, Case B says '2 - Different than' Case A)

² Cases are considered as matched on CDC match-strings if they match on last name soundex, date of birth, sex at birth, state and country of residence at HIV diagnosis (i.e., rsh) or state and country of residence at AIDS diagnosis (i.e., rsa)

RIDR reports are generated using data from the eHARS consolidated database on a semiannual basis. The list is generated by identifying cases reported by different jurisdictions but match on last name soundex (last\_name\_sndx), date of birth (dob), and sex at birth (birth\_sex) but have not been confirmed as the same or different persons by the local and state health departments. These potential interstate duplicate case reports are distributed to local and state health departments for resolution. In RIDR reports, at least one case in the potential interstate duplicate pair had to be reported during the six months prior to the generation of the report. To identify and resolve older potential interstate duplicates in the national dataset, CDC generated



and distributed the CIDR report in January 2018. CIDR reports contain all unresolved potential interstate duplicates regardless of when they were reported to CDC through December 2017.

The prerequisites (structural requirements), best practices (process standards), and outcome standard for interstate duplicate review are described next.

## Structural Requirements

1. Link to CSTE 2001-ID-04 Reciprocal (Interstate) Notification of HIV Cases (<https://cdn.ymaws.com/www.cste.org/resource/resmgr/PS1/2001-ID-04.pdf>).
2. HIV Surveillance System Software, eHARS.
3. Variables used for CDC matching string last name soundex (last\_name\_sndx), date of birth (dob), sex at birth (birth\_sex), and state of residence at diagnosis (rsh\_state\_cd or rsa\_state\_cd) or, if a non-US resident at time of diagnosis, country of residence at diagnosis (rsh\_country\_cd / rsa\_country\_cd).
4. Standard procedure for processing of CDC's Cumulative and Routine Interstate Duplicate Review reports (see file Instructions for Processing CDC's Duplicate Review Report\_YYYYMM labeled RIDR under Case Surveillance in SharePoint).
5. Case Residency Assignment Policies and Procedures (see Technical Guidance File *Date and Place of Residence*).
6. Procedures for evaluating accuracy of integrated HIV surveillance systems (see Technical Guidance File *Evaluation and Data Quality*).
7. Access to Secure Access Management Services; Current Digital Certificate.
8. Access to encryption software that meets federal Advanced Encryption Standard.

## Process Standards

### 1. Frequency of Procedure

Routine Interstate Duplicate Review must be performed semi-annually. Cumulative Interstate Duplicate Review must be completed over the course of the PS18-1802 funding cycle (2018-2022).

### 2. Duplicate Review of Out-of-Jurisdiction Cases

States should maintain information on out-of-jurisdiction cases in eHARS. To determine if a pair in the RIDR/CIDR report represents the same person or different persons, contact the other state's surveillance coordinator (or his or her designees) to compare and collect additional information. Questions to ask to determine if pairs are the same or different persons might include:

- Do the cases share the same name, including considerations of other available name types (e.g., alias)?
- Does the Social Security Number prefix come from the other state?

- Are there any comments that reference the other state?
- Is there a death date match?
- Is there a current residence match?
- Is there an unusual mode of exposure?

### **3. Records that Represent the Same Person**

If, after discussion with the other state’s surveillance coordinator (or his or her designees), the cases are deemed to represent the same person, case residency at diagnosis must be established for the pair. Use policies and procedures for state of residence at diagnosis to ensure that cases are counted appropriately (see Technical Guidance File *Date and Place of Residence*). Once state of residence is established, jurisdictions should inform CDC of the duplicate review resolution by updating the data elements in the Duplicate Review tab of the ACRF or PCRf document (i.e., select “1-same as” for duplicate status, etc.) as well as the residency at diagnosis information (i.e., rsh\_state\_cd / rsh\_country\_cd and rsa\_state\_cd / rsa\_country\_cd [if the person has a diagnosis of stage 3 AIDS Diagnosis]).

In addition to updating the residence at diagnosis and information on the Duplicate Review tab, jurisdictions are encouraged to share with each other additional information about the case in accordance with their respective reporting and data sharing laws and regulations. Such information may include risk factors, AIDS-defining conditions, vital status, date of death, last negative test result, if nucleotide sequences are available, care status etc. In particular, surveillance staff from each jurisdiction should help each other determine in which jurisdiction does the patient currently reside and enter the address information into the Identification tab of the ACRF or PCRf document in eHARS.

### **4. Records that Represent Different Persons**

If, after discussion with the other state’s surveillance coordinator (or his or her designees), the cases are deemed to represent different persons, jurisdictions should inform CDC of the duplicate review resolution by updating the data elements in the Duplicate Review tab of the ACRF or PCRf document (i.e., select “2 – Different than” for duplicate status, etc.).

### **5. Resolution of Potential Duplicates**

100% of potential interstate duplicate pairs in the RIDR/CIDR reports should be resolved and duplicate status updated in eHARS in the following timeframes:

- RIDR report released in January should be completed by June of the same year.
- RIDR report released in July should be completed by December of the same year.
- CIDR report released in January 2018 should be completed by December 2022, with at least 20% of duplicates resolved each year.

Staff approved to release information about HIV cases to other jurisdictions can be found on the CSTE HIV/AIDS Contact Board Web site. Please contact the HIV surveillance support staff at CSTE for information on obtaining sign-on identifications and passwords to access the web site (<https://www.cste.org/page/HIVContact>); the CSTE point of contact can be reached at 770-458-3811.

Contact the CDC's designated subject matter expert (SME) for RIDR/CIDR for any questions related to the RIDR/CIDR process. The RIDR/CIDR SME may be reached through the CDC HIV Surveillance Branch's main number (404-639-2050) or through the CDC epidemiologist assigned to your jurisdiction for technical assistance support.

## **Outcome Standard**

- Of all pairs on the Routine Interstate Duplicate Review (RIDR) list, at least ( $\geq$ ) 98% were resolved, assessed at the end of each RIDR cycle.
- Of all pairs on the Cumulative Interstate Duplicate Review (CIDR) list, at least ( $\geq$ ) 20% are resolved annually by December of each of the 5 years of the funding cycle and the duplicate status updated in eHARS at the end of December each year of the funding cycle (2018-2022). At the end of PS18-1802 (December 2022), 100% of all CIDR pairs are completed, assessed at the end of 2022.

## **National HIV Surveillance System (NHSS)**

### **Attachment 4(d)**

Data to Care Reporting Guidance for PS18-1802 and PS20-2010 Recipients

# **Data-to-Care Reporting Guidance**

Centers for Disease Control and Prevention

Division of HIV/AIDS Prevention

Data to Care Evaluation Workgroup

January, 2019 (revised June 2021)

# Data-to-Care Reporting Guidance

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# Data-to-Care Reporting Guidance

## Summary

The Centers for Disease Control and Prevention (CDC) needs accurate reporting of three key Data-to-Care (D2C) outcome indicators to monitor and evaluate outcomes for CDC funded programs, ensure accountability for funds appropriated by the U.S. Congress for HIV prevention, and inform the Division of HIV/AIDS Prevention's (DHAP) planning. The three D2C indicators described in this document are included in the PS18-1802 Evaluation and Performance Measurement Plan (EPMP) under Strategy 4 and also in the PS20-2010 EPMP under the Treat Strategy. To monitor and evaluate D2C outcomes among those Not-In-Care (NIC), CDC has developed a logic model that includes the six main operational steps of D2C NIC investigations and added 10 variables to eHARS to evaluate D2C NIC programs. These variables are located in the eHARS Adult Case Report Form (ACRF) document under the "Follow-up Investigation" tab in eHARS version 4.10.5 and later. Further details about each variable may be found in the eHARS Technical Reference Guide (TRG).

- This guidance updates previous Data-to-Care Guidance for PS18-1802 Recipients January 2019 and may be used to guide reporting and evaluation of other D2C funded programs (e.g., PS20-2010).
- Since January 2019, all health departments receiving CDC funds (e.g., PS18-1802, PS20-2010) must collect data for the 10 D2C NIC variables.
- Health departments must enter or import D2C NIC data into eHARS at least twice yearly, by the June and December eHARS data transfers.
- Data transfers should include all records for which an investigation was opened. They should not be limited to just those records for which an investigation has been completed.

## Preparation of this Document

The Division of HIV/AIDS Prevention (DHAP), Centers for Disease Control and Prevention, led the development of Data-to-Care indicators previously described in the PS18-1802 Evaluation and Performance Measurement Plan. DHAP then requested the input of PS18-1802 recipients on how to accurately measure and report these variables and held a series of webinars in the summer and fall of 2018. The resulting document is the culmination of this collaboration between DHAP and PS18-1802 health departments including: Alaska, Colorado, District of Columbia, Louisiana, Maryland, Michigan, Nebraska, New Jersey, New York State, Philadelphia, San Francisco, South Carolina, Tennessee, Washington, and Wisconsin. DHAP would like to acknowledge the essential role staff from these health departments provided in order to finalize the first guidance document. The document was revised in June 2021 by DHAP to expand the scope to accommodate additional NOFOs funding D2C programs and provide additional guidance.

## ***Main Steps in Data-to-Care Not-in-Care Programs***

The graphic below depicts the six main operational steps involved in a D2C NIC program.





## Data-to-Care Not-in-Care Logic Model

The logic model for the D2C NIC strategy is shown below. CDC has identified two short-term and one intermediate intended outcomes—indicated with bold font in the logic model—that will be followed for monitoring D2C NIC program outcomes at the national and jurisdictional level.

Data-to-Care Logic Model: Identifying persons diagnosed with HIV who are not in HIV medical care and linking them to care			
Activities	Outputs	Short-term Intended Outcomes	Intermediate & Long-term Intended Outcomes
<b>Step 1 – Identification</b> <ul style="list-style-type: none"> <li>Generate a list of persons with HIV (PWH) presumed not to be in HIV medical care</li> </ul>	<ul style="list-style-type: none"> <li># of persons presumed not to be in HIV medical care</li> </ul>	<ul style="list-style-type: none"> <li><b>Increased identification of PWH who are not in HIV medical care</b></li> </ul>	
<b>Step 2 – Investigation</b> <ul style="list-style-type: none"> <li>Use other data sources to investigate care status</li> <li>Prioritize list for outreach</li> <li>Conduct outreach to locate, contact, and interview persons on prioritized list to verify care status</li> </ul>	<ul style="list-style-type: none"> <li># of persons prioritized for outreach</li> <li># of persons located, contacted, and interviewed</li> <li># of persons confirmed not to be in HIV medical care</li> </ul>		
<b>Step 3 – Linkage to Care</b> <ul style="list-style-type: none"> <li>Link persons confirmed not to be in care to HIV medical care</li> </ul>	<ul style="list-style-type: none"> <li># of persons linked to HIV medical care</li> </ul>	<ul style="list-style-type: none"> <li><b>Increased linkage to and retention in HIV medical care among PWH</b></li> </ul>	<ul style="list-style-type: none"> <li><b>Increased HIV viral load suppression among PWH</b></li> <li>Improved health outcomes for PWH</li> <li>Reduced HIV transmission</li> </ul>
<b>Step 4 – Support Services</b> <ul style="list-style-type: none"> <li>Link to support services that facilitate retention in HIV medical care and adherence to treatment</li> </ul>	<ul style="list-style-type: none"> <li># of persons linked to support services that facilitate retention in HIV medical care and adherence to treatment</li> </ul>	<ul style="list-style-type: none"> <li>Increased linkage of PWH to support services that facilitate retention in HIV medical care and adherence to treatment</li> </ul>	
<b>Step 5 – HIV Prevention Services</b> <ul style="list-style-type: none"> <li>Provide or link to HIV prevention services, including partner services</li> </ul>	<ul style="list-style-type: none"> <li># of persons provided or linked to HIV prevention services, including partner services</li> </ul>	<ul style="list-style-type: none"> <li>Increased provision of or linkage to HIV prevention services, including partner services</li> </ul>	
<b>Step 6 – Feedback Loop</b> <ul style="list-style-type: none"> <li>Update surveillance data with information obtained through data-to-care process</li> </ul>	<ul style="list-style-type: none"> <li># of surveillance records updated</li> </ul>	<ul style="list-style-type: none"> <li>Increased completeness, timeliness, and quality of HIV surveillance data</li> </ul>	<ul style="list-style-type: none"> <li>Improved usefulness of HIV surveillance data for identifying PWH who are not in HIV medical care</li> </ul>

## Evaluation Questions

CDC has identified three evaluation questions to address at the national level:

- To what extent are D2C programs accurately identifying PWH who are not in HIV medical care?
- To what extent are D2C programs linking not-in-care PWH to HIV medical care?
- To what extent do PWH who are linked to HIV medical care through D2C programs achieve viral suppression?

## Indicators

CDC will be tracking three key indicators to measure the three outcomes selected for monitoring D2C NIC program outcomes at the national and jurisdictional level. These indicators, and the numerators and denominators needed to calculate them, are shown in the table below. A SAS program will be made available for health departments to generate these indicators from eHARS locally for local use. Health departments may identify additional measures or indicators to follow at the local level, based on specific jurisdictional needs or special populations their programs are aiming to reach. See Evaluation and Performance Measurement plans for description of specific NOFO requirements.

**Table 1. Key data-to-care not-in-care outcome indicators**

Intended Outcome	Evaluation Question	Indicator	Numerator & Denominator
Increased identification of PWH who are not in HIV medical care.	To what extent are health departments able to use HIV surveillance and other data to identify PWH who are not in HIV medical care?	<b><u>D2C NIC Identification:</u></b> Percentage of presumptively not-in-care PWH with an investigation opened (initiated) during a specified 6-month evaluation time period, who were confirmed within 90 days after the investigation was opened not to be in care	<b><u>Denominator:</u></b> Number of presumptively not-in-care PWH with an investigation opened (initiated) during a specified 6-month evaluation time period
			<b><u>Numerator:</u></b> Of those in the denominator, the number confirmed within 90 days after the investigation was opened not to be in care
Increased linkage to HIV medical care among PWH identified through D2C activities.	To what extent are health departments able to link to HIV medical care PWH who are confirmed through D2C activities not to be in care?	<b><u>D2C NIC Linkage:</u></b> Percentage of PWH confirmed during a specified 6-month evaluation time period not to be in care, who were linked to HIV medical care within 30 days after being confirmed not to be in care	<b><u>Denominator:</u></b> Number of PWH confirmed during a specified 6-month evaluation time period not to be in care
			<b><u>Numerator:</u></b> Of those in the denominator, the number linked to HIV medical care within 30 days after being confirmed not to be in care
Increased HIV viral load suppression among PWH identified through D2C activities.	To what extent is HIV viral load suppression achieved among PWH who are linked to HIV medical care after	<b><u>D2C NIC Viral Suppression:</u></b> Percentage of PWH linked to HIV medical care during a specified 6-month evaluation time period,	<b><u>Denominator:</u></b> Number of PWH linked to HIV medical care during a specified 6-month evaluation time period

Intended Outcome	Evaluation Question	Indicator	Numerator & Denominator
	being confirmed through D2C activities not to be in care?	who achieved HIV viral suppression within six months (180 days) after being linked to care	<b>Numerator:</b> Of those in the denominator, the number who achieved HIV viral suppression within six months (180 days) after being linked to care

### Variables Needed to Assess Key Outcome Indicators

To calculate outcome indicators, it is necessary to collect and enter in eHARS the data needed to perform the calculations. For example, the “identification” indicator, which can be used to monitor progress in using HIV surveillance and other data to accurately identify PWH who are not in HIV medical care, measures the percentage of presumptively not-in-care PWH with a D2C NIC investigation opened (initiated) during a specified 6-month evaluation time period that were confirmed not to be in care. To calculate this indicator, the following information must be collected:

- The date the person was placed on the presumptive NIC list
- Whether a not-in-care investigation was opened (initiated)
- If a not-in-care investigation was opened, the date it was opened
- For those with an investigation opened, whether the person was confirmed not to be in care
- If they were confirmed not to be in care, the date this determination was made

CDC has added 10 variables to eHARS for which health departments receiving CDC funds must collect and report data so their D2C NIC indicators can be calculated. The table below presents the new variables, along with their labels, value options and definitions. Health departments planning to monitor additional indicators as part of their local D2C evaluations will need to identify the variables needed for calculating their local-use indicators and collect those data for those variables, as well.

**Table 2. Data-to-care not-in-care data elements and definitions**

Data element	Variable	Definition
<b>Data element 1</b> ( <i>invest_type_cd</i> )	<b>Type of investigation</b>	
	0 – Transmission cluster (TC)	
	1 – Not in care (NIC)	
<b>Data element 2</b> ( <i>invest_ident_method</i> )	<b>How person was first identified as NIC (presumptively or confirmed)?</b>	The source from which you have identified the person as NIC.
	01 - Health department HIV surveillance system (e.g., eHARS)	By using data in a “self-contained” HIV surveillance system only.
	02 – Health department integrated data system	By using data in an integrated data system, which contains HIV surveillance data as well as other types of data (e.g., care data), or by running an application that automatically integrates data from multiple sources, such as eHARS, CAREWare, and Medicaid databases.
	03 – Provider report	By a health care provider.
	04 – Transmission cluster investigation	Through the investigation of a transmission cluster.

Data element	Variable	Definition
	05 – Elevated viral load investigation	Through the investigation of persons with elevated HIV viral load.
	06 – Partner services investigation	Through partner services investigations.
	07 – Medical Monitoring Project (MMP)	Through MMP activities (e.g., MMP participant interview).
	88 – Other	Other sources that do not fit in any of the above.
<b>Data element 3</b> (invest_ident_dt)	<b>Date first identified as not in care (presumptively or confirmed)</b>	
<b>Data element 4</b> (invest_incl)	<b>Included for investigation?</b>	Was the person included in or excluded from investigation to confirm their care status?
	Y – Included in investigation	Health department made further efforts to investigate after person was placed on presumptive NIC list. This may include (but is not limited to) matching the <b>presumptive</b> NIC list to other data systems or programs to determine residence, vital status, and care status; or conducting a field investigation.
	N – Excluded from investigation	Did not meet programmatic criteria for follow-up.
<b>Data element 5</b> (invest_start_dt)	<b>Date investigation opened*</b>	If feasible to collect, this is the earliest date that any investigation was conducted following generation of the presumptive NIC list (regardless of whether the presumptive NIC list was generated from a “self-contained” HIV surveillance system or an integrated system). If field investigation, this would be the <b>date the field investigation began</b> . If matching with other data, it would be the date the database or record search began. <b>If both a field investigation and database or record search are conducted, you would use the earlier of the two dates.</b>
<b>Data element 6</b> (invest_dispo)	<b>Disposition, care status investigation</b>	Result of the investigation.
	1 – Deceased	There is evidence that the person is dead (you will be prompted to update the person’s vital status and date of death in eHARS).
	2 – Resides out of jurisdiction	There is evidence that the person resides outside of the D2C catchment area defined by the health department (you will be prompted to add the out-of-jurisdiction address into eHARS).
	3 – In care	There is either laboratory (in eHARS), self-report, or other evidence that the person is receiving regular HIV medical care.
	4 – Not in care (confirmed)	Confirmed <b>with the person</b> that he or she is indeed NIC.
	5 – Unable to determine	Unable to obtain adequate information to determine care status.
<b>Data element 7</b> (invest_dispo_dt)	<b>Investigation disposition date</b>	Date a person’s care status disposition was determined.
<b>Data element 8</b>	<b>Basis of care status investigation disposition</b>	How was the care status disposition determined?

Data element	Variable	Definition
<i>(invest_dispo_method)</i>	1 – Database/record search, only	Health department only searched databases for residential location, vital status, and care status and did not conduct field investigation or contact the individual.
	2 – Patient contact/field investigation, only	Health department learned the person’s residential location, vital status, and care status only through field investigation or contacting the health care provider or the individual.
	3 – Database/record search and patient contact/ field investigation	A combination of the above two methods.
<b>Data element 9</b> <i>(int_dispo)</i>	<b>Disposition, linkage or re-engagement intervention</b>	<u>Linkage or re-engagement intervention</u> – Defined as an action taken by the program to facilitate a client’s entry or re-entry into HIV medical care (e.g., ARTAS, scheduling the appointment, reminding the client of the appointment, accompanying the client to their appointment, follow-up to ensure that the appointment took place). <u>Linked to or re-engaged in care</u> – Defined as the client attending an appointment for HIV medical care after having been identified as being NIC.
	1 – No intervention initiated	Program did not offer any linkage or re-engagement intervention to the client.
	2 – Linkage/re-engagement intervention declined by client	Program offered intervention, but it was declined by the client.
	3 – Returned to care before intervention was initiated	The client entered or resumed care without any additional linkage intervention.
	4 – Linkage/re-engagement intervention initiated; client was not successfully linked to/re-engaged in care	The client did not enter or resume care, despite the program’s intervention efforts.
	5 – Linked to/re-engaged in care, documented	The client was linked to/re-engaged in care by the program’s intervention, and this was confirmed through documentation [e.g., laboratory data, report from medical care provider (verbal or written), medical record review, other record review, other database, ARV prescription filled or refilled].
	6 – Linked to/re-engaged in care, client self-report, only	The client was apparently linked to/re-engaged in care by the program’s intervention, but this was determined only through client’s self-report, without any additional confirmation
	7 – Linkage/re-engagement status unknown	It is unknown whether the client entered or returned to care.

Data element	Variable	Definition
<b>Data element 10</b> <i>(int_dispo_dt)</i>	<b>Date returned to, linked to, or re-engaged in care</b>	<p><b>If return, linkage, or re-engagement was confirmed:</b>  Date of documented evidence that client attended an HIV medical care appointment after being identified as NIC (e.g., laboratory report, verbal or written report from medical care provider, medical record review, other record review, other database, ARV prescription filled or refilled).</p> <p><b>If return, linkage, or re-engagement was determined by client self-report, only:</b>  Date client reports having attended an HIV medical care appointment after being identified as NIC.</p>

\* In eHARS, only the term “opened” is used in reference to the investigation; however, the terms “opened” and “initiated” are synonymous.

## Methods for Calculating Key Outcome Indicators

The table below shows the methods for calculating each of the three key outcome indicators. An example of the evaluation time period  $[E_1, E_2]$  could be [07/01/2019, 12/31/2019].

**Table 3. Data-to-care not-in-care indicators, numerators, denominators, and methods of calculation**

Indicators	Numerators & Denominators	Methods of Calculation
<b>Identification:</b> Percentage of presumptively not-in-care PWH with an investigation opened (initiated) during a specified 6-month evaluation time period, who were confirmed within 90 days after the investigation was opened not to be in HIV medical care	<b>Denominator:</b> Number of presumptively not-in-care PWH with an investigation opened (initiated) during the evaluation time period $[E_1, E_2]$	Total number of unique cases satisfying the following criteria: <ul style="list-style-type: none"> <li><math>invest\_ident\_method = "01"</math> or <math>"02"</math> or <math>"03,"</math> and</li> <li><math>invest\_incl = "Y"</math> and <math>E_1 \leq invest\_start\_dt \leq E_2</math></li> </ul>
	<b>Numerator:</b> Of those in the denominator, the number confirmed within 90 days after the investigation was opened not to be in HIV medical care	Of the cases satisfying the above criteria, the number of cases with: <ul style="list-style-type: none"> <li><math>invest\_dispo = "4"</math> and</li> <li><math>invest\_dispo\_dt - invest\_start\_dt \leq 90</math> days</li> </ul>
<b>Linkage:</b> Percentage of PWH confirmed through D2C activities during a specified 6-month evaluation time period not to be in care, who were linked to HIV medical care within 30 days after being confirmed not to be in HIV medical care	<b>Denominator:</b> Number of PWH confirmed during the evaluation time period $[E_1, E_2]$ not to be in HIV medical care	Total number of unique cases satisfying the following criteria: <ul style="list-style-type: none"> <li><math>invest\_ident\_method = "01"</math> or <math>"02"</math> or <math>"03,"</math> and</li> <li><math>invest\_dispo = "4"</math> and <math>E_1 \leq invest\_dispo\_dt \leq E_2</math></li> </ul>
	<b>Numerator:</b> Of those in the denominator, the number linked to HIV medical care within 30 days after being confirmed not to be in HIV medical care	Of the cases satisfying the above criteria, the number of cases with: <ul style="list-style-type: none"> <li><math>int\_dispo = "3", "5"</math> or <math>"6",</math> and</li> <li><math>int\_dispo\_dt - invest\_dispo\_dt \leq 30</math> days</li> </ul>
<b>Viral suppression:</b> Percentage of PWH linked through D2C activities to HIV medical care during a specified 6-month evaluation time period, who achieved HIV viral suppression within six months (180 days) after being linked to HIV medical care	<b>Denominator:</b> Number of PWH linked to HIV medical care during the evaluation time period $[E_1, E_2]$	Total number of unique cases satisfying the following criteria: <ul style="list-style-type: none"> <li><math>invest\_ident\_method = "01"</math> or <math>"02"</math> or <math>"03,"</math> and</li> <li><math>int\_dispo = "3", "5"</math> or <math>"6",</math> and</li> <li><math>invest\_dispo = "4"</math></li> <li><math>E_1 \leq int\_dispo\_dt \leq E_2</math></li> </ul>
	<b>Numerator:</b> Of those in the denominator, the number who achieved HIV viral suppression within six months (180 days) after being linked to HIV medical care	Of the cases satisfying the above criteria, the number of cases with: <ul style="list-style-type: none"> <li><math>sample\_dt - int\_dispo\_dt \leq 180</math> days</li> </ul> [where $sample\_dt$ is the earliest specimen collection date that is on or after $int\_dispo\_dt$ and is associated with an HIV-1 viral load test result that is below ( $<$ ) 200 copies/mL or the result interpretation is below detection limit]

## *Collecting Data for Data-to-Care Not-in-Care Variables*

Health departments implementing D2C NIC programs can use a variety of approaches for tracking activities and outcomes. Some programs have developed unique electronic case management systems, some have created databases using commercial software programs (e.g., Excel, REDCap, Access), some may opt to use eHARS. Health departments should identify best practices to facilitate tracking activities and outcomes. Health departments with existing D2C databases should crosswalk the 10 eHARS D2C NIC variables with their current D2C databases and modify or add variables in their current databases, as necessary. Data may be extracted from these databases and electronically imported into eHARS. Health departments newly implementing D2C NIC programs and developing local D2C data systems should ensure that the 10 eHARS D2C NIC variables are included in these systems.

The eHARS D2C NIC variables are not included on the hard copy of the CDC Adult Case Report Form (ACRF) and health departments are not required to document this information in hard copy. However, for some D2C workers documenting the information for the variables in hard copy can facilitate this process. On the following page is an example of a template that includes all the eHARS D2C NIC variables, labels and skip patterns. This example template can be tailored to suit jurisdictional data collection needs and can also be used by health departments with existing systems for cross-walking purposes. Spending time up front to ensure variables in local systems are comparable and data are extracted correctly will help ensure that high quality data are reported and used for evaluation.

Understanding the definitions of the D2C NIC variables will ensure that the data entered into D2C data systems are reliable, standardized, consistent, and valid. If there are different interpretations of the definition of variables in the systems used or by staff, the indicators calculated in eHARS from the D2C NIC data may not accurately reflect program performance. Training and guidance may include:

- a. Definitions of variables and response options
- b. Rationale for why each variable is collected and how variables may be used to answer specific questions
- c. Explanation of skip patterns and conditional relationships between variables
- d. Description of the data collection process and tips for avoiding common errors during data collection

Finally, it is important to solicit and incorporate feedback from staff and system users about the data collection and import/entry processes in the beginning and throughout the project period.



## Example of a data collection tool that could be used for collecting data during data-to-care not-in-care investigations

<b>1. How person was first identified as not in care <i>invest_ident_method</i></b>																							
<input type="checkbox"/> 01- Health department HIV surveillance system (e.g., eHARS) ( <i>go to #2</i> )  <input type="checkbox"/> 02- Health department integrated data system ( <i>go to #2</i> )	<input type="checkbox"/> 03- Provider report ( <i>go to #2</i> )  <input type="checkbox"/> 04- Transmission cluster investigation ( <i>go to #2 and then #7</i> )  <input type="checkbox"/> 05- Elevated viral load investigation ( <i>go to #2 and then #7</i> )	<input type="checkbox"/> 06- Partner services investigation ( <i>go to #2 and then #7</i> )  <input type="checkbox"/> 07- Medical Monitoring Project (MMP) ( <i>go to #2 and then #7</i> )  <input type="checkbox"/> 88- Other ( <i>go to #2</i> )																					
<b>2. Date first identified as not in care <i>invest_ident_dt</i></b>								M	M	D	D	Y	Y	Y	Y								
<b>3. Included for investigation? <i>invest_incl</i> (Date investigation opened <i>invest_start_dt</i>)</b>																							
<input type="checkbox"/> Yes → <i>Date investigation opened</i>								M	M	D	D	Y	Y	Y	Y	<input type="checkbox"/> No ( <i>Excluded → Stop Here</i> )							
<b>4. Disposition, care status investigation <i>invest_dispo</i></b>																							
<input type="checkbox"/> 1- Deceased ( <i>go to #5 - 6 and then STOP</i> )  <input type="checkbox"/> 2- Resides out of jurisdiction ( <i>go to #5 - 6 and then STOP</i> )  <input type="checkbox"/> 3- In care ( <i>go to #5 - 6 and then STOP</i> )								<input type="checkbox"/> 4- Not in care (confirmed) ( <i>go to #5 - 7 and linkage date if linked</i> )  <input type="checkbox"/> 5- Unable to determine ( <i>go to #5 - 6 and then STOP</i> )															
<b>5. Investigation disposition date <i>invest_dispo_dt</i></b>												M	M	D	D	Y	Y	Y	Y				
<b>6. Basis of care status disposition? (Optional) <i>invest_dispo_method</i></b>																							
<input type="checkbox"/> 1- Database/record search, <u>only</u>  <input type="checkbox"/> 2- Patient contact/field investigation, <u>only</u>								<input type="checkbox"/> 3- Database/record search <u>and</u> patient contact/field investigation															
<b>7. Disposition, linkage or re-engagement intervention (answer only if confirmed not in care) <i>int_dispo</i></b>																							
<input type="checkbox"/> 3- Returned to care before intervention was initiated  <input type="checkbox"/> 5- Linked to/re-engaged in care, documented*  <input type="checkbox"/> 6- Linked to/re-engaged in care, client self-report, only								<input type="checkbox"/> 1- No intervention initiated  <input type="checkbox"/> 2- Linkage/re-engagement intervention declined by client  <input type="checkbox"/> 4- Linkage/re-engagement intervention initiated, not successfully linked to/re-engaged in care  <input type="checkbox"/> 7- Linkage/re-engagement status unknown															
								<div style="text-align: center;">             Date returned to, linked to, or re-engaged in care <i>int_dispo_dt</i> </div> <table border="1" style="margin: 0 auto; border-collapse: collapse;"> <tr> <td>M</td><td>M</td><td>D</td><td>D</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>								M	M	D	D	Y	Y	Y	Y
M	M	D	D	Y	Y	Y	Y																

\*Examples of types of documentation: laboratory data, report from medical care provider (verbal or written), medical record review, other record review, other database, ARV prescription filled or refilled.

## Reporting Data for Data-to-Care Not-in-Care Variables to CDC via eHARS

The 10 variables CDC has added to eHARS, for which recipients are required to collect and report data for evaluation of their D2C programs, are located in the eHARS Adult Case Report Form (ACRF) document under the “Follow-up Investigation” tab in eHARS version 4.10.5 and later. Further details about each variable may be found in the eHARS Technical Reference Guide (TRG). Note, programs may include children (i.e., under 13 years of age) in their D2C NIC investigations. Outcomes for these investigations should be reported by creating an ACRF and documenting the 10 variables under the “Follow-up Investigation” tab as done for adults.

CDC needs accurate reporting of the three key D2C NIC outcome indicators to monitor and evaluate outcomes for D2C programs, ensure accountability for funds appropriated by the U.S. Congress for HIV prevention, and inform DHAP’s planning. Data transfers should include all records for which an investigation was opened. They should not be limited to just those records for which an investigation has been completed. Health departments will enter or import D2C NIC data into eHARS at least twice yearly, by the June and December eHARS data transfers (see table below).

**Table 4. Example data-to-care not-in-care data: availability and reporting timeline**

	Indicator 1: Confirmation of NIC status within 90 days after investigation opened	Indicator 2: Linkage to HIV medical care within 30 days after person confirmed NIC	Indicator 3: Achievement of viral suppression within 6 months (180 days) after person linked to care
<b>Evaluation Time Period 1: January 1 – June 30</b>			
Data available locally in jurisdictional databases <sup>1</sup>	October 31, Year X	August 31, Year X	January 31, Year X+1
Data entered or uploaded into eHARS	December data transfer, Year X	December data transfer, Year X	June data transfer, Year X+1
<b>Evaluation Time Period 2: July 1 – December 31</b>			
Data available locally in jurisdictional databases <sup>1</sup>	April 30, Year X+1	February 28/29, Year X+1	July 31, Year X+1
Data entered or uploaded into eHARS	June data transfer, Year X+1	June data transfer, Year X+1	December data transfer, Year X+1

<sup>1</sup>Allowing 30 days for reporting and data entry

### ***Data Management and Quality Assurance of Data-to-Care Not-in-Care Data***

Routine quality assurance checks should be implemented on processes throughout the data life cycle to ensure completeness and timeliness of data—including data collection/documentation, data entry/import, and reporting data to CDC. Guidance for D2C NIC data management and quality assurance are forthcoming. Guidance and tools will be added to this document as they are developed.

### ***Data Security and Confidentiality***

All data used in D2C NIC activities should be handled in a secure and confidential manner in accordance with the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Data Security and Confidentiality Guidelines:

(<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>).

This includes all instances in which data are shared with partners internal and external to the health department. All partners should be made aware and comply with security and confidentiality guidelines and protocols, including how data should be transferred, stored, and used.

## ***Appendix***

Below are flow diagrams depicting the steps involved in identifying persons with HIV who are not in HIV medical care and linking them to care in two models: the Health Department Model (Figure 1) and the Collaborative Model (Figure 2). These diagrams were used as a basis for CDC's data-to-care (D2C) not-in-care (NIC) evaluation and may be helpful to some health departments as they flesh out their D2C NIC program descriptions.

**Figure 1. Data-to-Care Health Department Model: Key Steps**

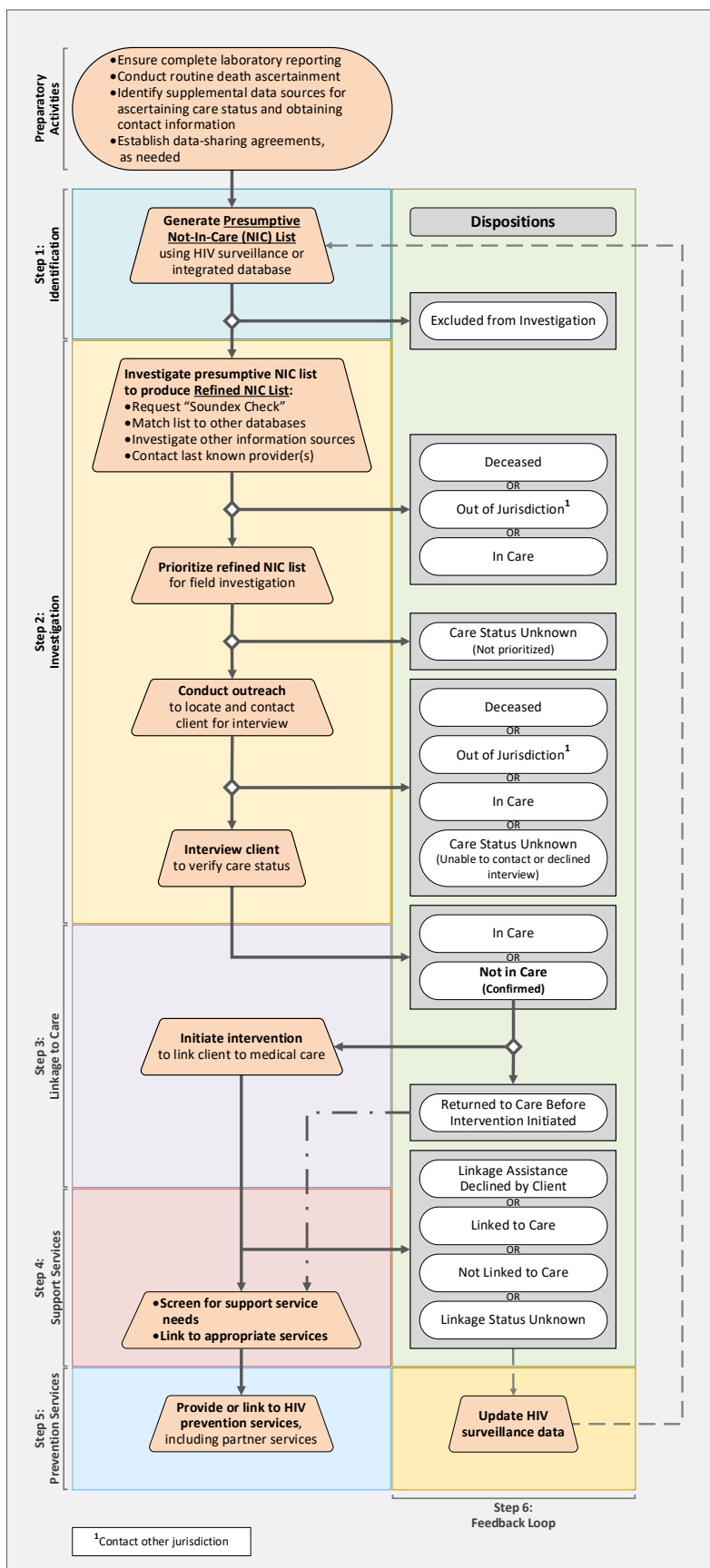
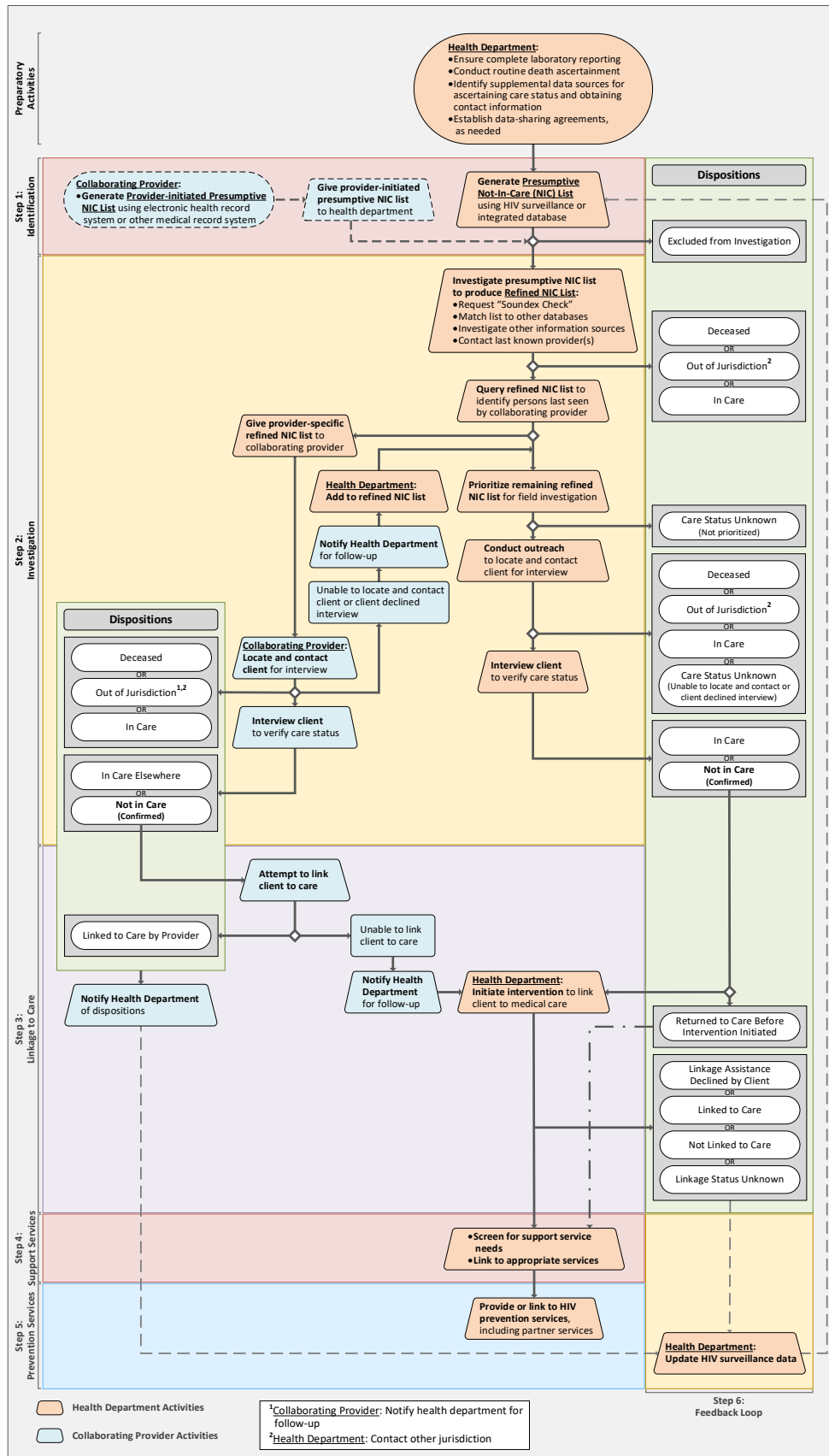


Figure 2. Data-to-Care Collaborative Model: Key Steps



## **National HIV Surveillance System (NHSS)**

### **Attachment 4 (e)**

#### **Technical Guidance for HIV Surveillance Programs: Detecting HIV Transmission Clusters**

# Technical Guidance for HIV Surveillance Programs

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## Detecting HIV Transmission Clusters

HIV Surveillance Branch  
Atlanta, Georgia



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# Introduction

A critical step toward bringing the nation closer to the goal of no new infections is identifying and responding to clusters of active, ongoing HIV transmission. HIV transmission clusters are groups of persons with HIV who have an epidemiological connection related to HIV transmission; clusters include persons with diagnosed or undiagnosed HIV. Such clusters can be identified through multiple approaches, including partner services, astute providers, and surveillance, including HIV nucleotide sequence data reported as part of HIV surveillance. Evidence shows that HIV surveillance can identify transmission clusters that would otherwise go unrecognized. Information about these transmission clusters and the associated risk networks can help us to focus proven HIV prevention tools where they are needed most. In this way, expanded use of HIV surveillance has the potential to significantly improve HIV prevention efforts.

This document describes the use of HIV surveillance data to detect transmission clusters through the identification of HIV diagnoses clustered in time and space (i.e., time-space clusters) and clusters of HIV infections with closely related strains (i.e., molecular clusters). It also describes the mechanisms behind detecting molecular clusters using HIV nucleotide sequence data and the relationship of a molecular cluster to the underlying transmission cluster and risk network. A brief introduction into the methodology behind time-space cluster detection is also presented.

The focus of this document is cluster detection; cluster response is covered elsewhere. See the [CDC's HIV cluster and outbreak detection and response webpage](#) for accompanying tools and resources regarding cluster and outbreak response.

## Definitions and context

### What is a transmission cluster?

- A **transmission cluster** is a group of persons with HIV (diagnosed or undiagnosed HIV) who are connected by HIV transmission. Transmission clusters can represent recent and ongoing HIV transmission in a population, and prevention efforts could prevent new infections. The section [How can identifying transmission clusters help focus prevention efforts?](#), describes the importance of identifying transmission clusters for prevention efforts in more detail.
- A transmission cluster represents a subset of a **risk network**. A risk network includes the group of persons among whom HIV transmission has occurred and could be ongoing. This network includes persons who are not HIV infected but may be vulnerable to infection, as well as persons with HIV who are in the transmission cluster. Transmission clusters present opportunities for prevention in the larger risk network.
- Transmission clusters can be identified through multiple mechanisms:
  - **HIV case surveillance data.** An increase in diagnoses in a particular geographic area or population (i.e., a time-space cluster). In areas with low incidence of HIV (like many rural communities in the United States), transmission clusters might be more easily detected through HIV case surveillance. Improved timeliness of reporting may improve a jurisdiction's ability to detect a transmission cluster. It is important to note, however, that an increase in the number of diagnoses may not reflect an increase in transmission. Rather, an increase in diagnoses may reflect an increase in HIV testing that has diagnosed infections that may be longstanding. The use of HIV

case surveillance data to identify transmission clusters is discussed in more detail in the section [Cluster detection methods](#).

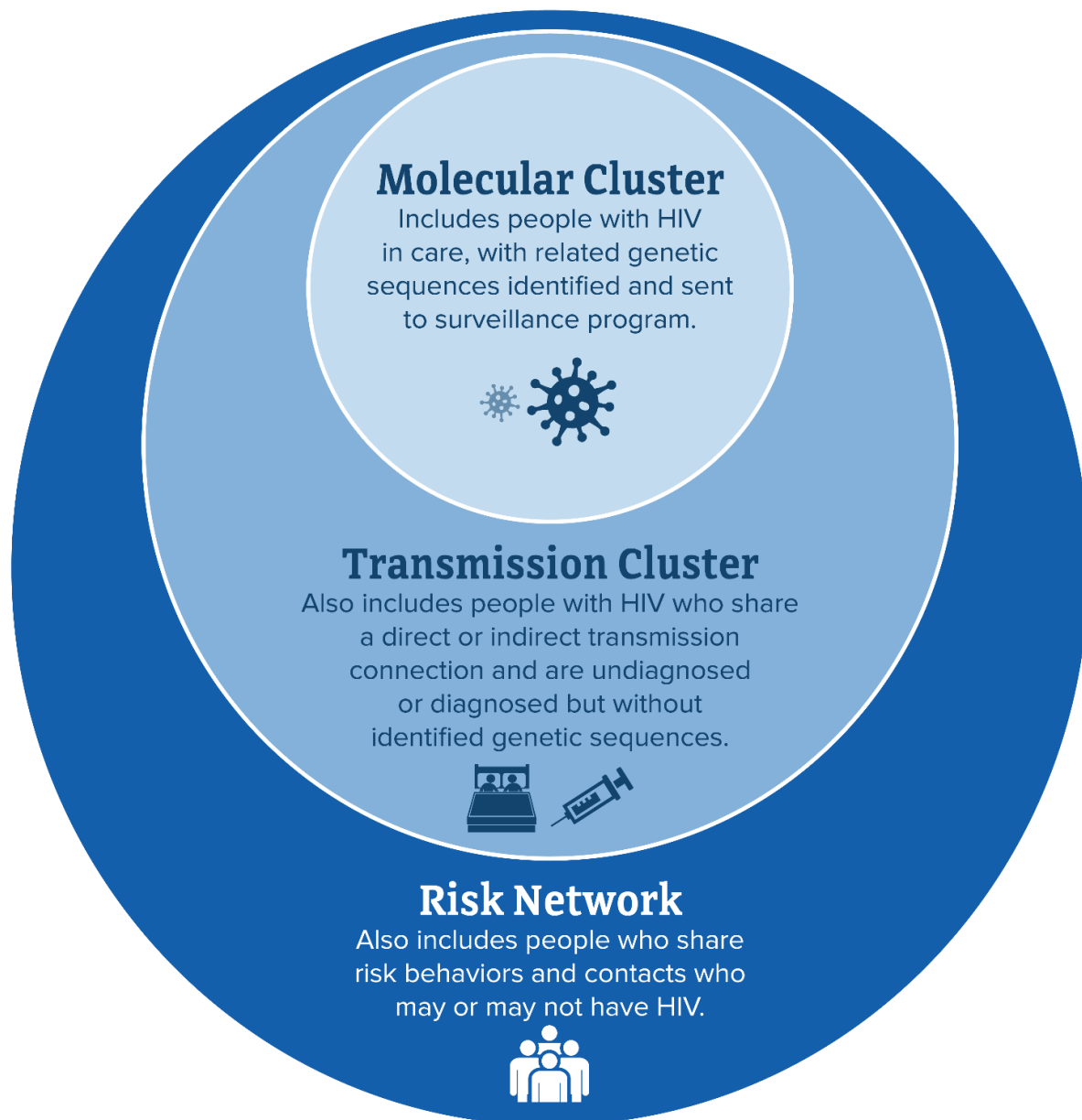
- **HIV partner services and contact investigations.** Partner services staff (referred to as disease intervention specialists [DIS] in many jurisdictions) routinely perform investigations for persons with newly diagnosed HIV infection, interviewing them to elicit information about their partners, who can then be confidentially notified of possible exposure and potential risk. Partner services activities can also include prevention counseling, testing for HIV and STDs, and linkage or referral to medical care. Because DIS work intensively in local communities, they are positioned to notice unexpected patterns or increases in HIV diagnoses.
- **Molecular HIV sequence data.** Analysis of molecular HIV sequence data reported to surveillance can identify clusters of cases with closely related HIV strains (i.e., molecular clusters). This method may be particularly useful in identifying transmission clusters that are not detected through other mechanisms. Examples include transmission clusters occurring in an area with a high incidence of HIV infection, that involve multiple jurisdictions, or that are in populations in which persons do not provide contact tracing information to DIS.
- **Astute health department staff, care providers, or community members.** HIV transmission clusters may be initially detected through astute observations from frontline staff at the health department or clinical providers. Observations of increases in HIV diagnoses call for further investigation to determine if and how these persons are connected and the extent of other connections they may have in a community.

## What is a molecular cluster, and how does it relate to a transmission cluster?

- Identification of **molecular clusters** provides a tool to identify transmission clusters. A **molecular cluster** is a group of persons with diagnosed and genetically similar HIV infection. HIV is constantly evolving; therefore, persons whose HIV infections are genetically similar may be closely related by transmission. For more information on HIV evolution, see [Appendix B](#).
- A **molecular cluster** contains only those people for whom molecular data are available and can be analyzed; it is typically a subset of a larger transmission cluster.
- Molecular clusters are identified through analysis of HIV molecular sequence data, information that is generated from HIV drug-resistance testing. Drug-resistance testing is conducted to identify mutations in HIV associated with resistance to HIV antiretroviral medications and to help the HIV care provider select an appropriate treatment regimen. This testing is recommended for all persons with diagnosed HIV infection and should be conducted at entry to HIV care.
- As a result, molecular clusters include persons with diagnosed HIV infection who have entered care, have had genetic resistance testing, and have had sequences transmitted to the health department for analysis.
- A molecular cluster is typically a subset of a larger transmission cluster, which can also include:
  - Persons with diagnosed HIV infection who do not have a sequence available for analysis because:
    - They did not enter care
    - They entered care, but have not had a genetic resistance test
    - They entered care and have had a genetic resistance test, but the sequence was not transmitted to the health department for analysis, or was of poor quality and could not be analyzed
  - Persons with undiagnosed infection

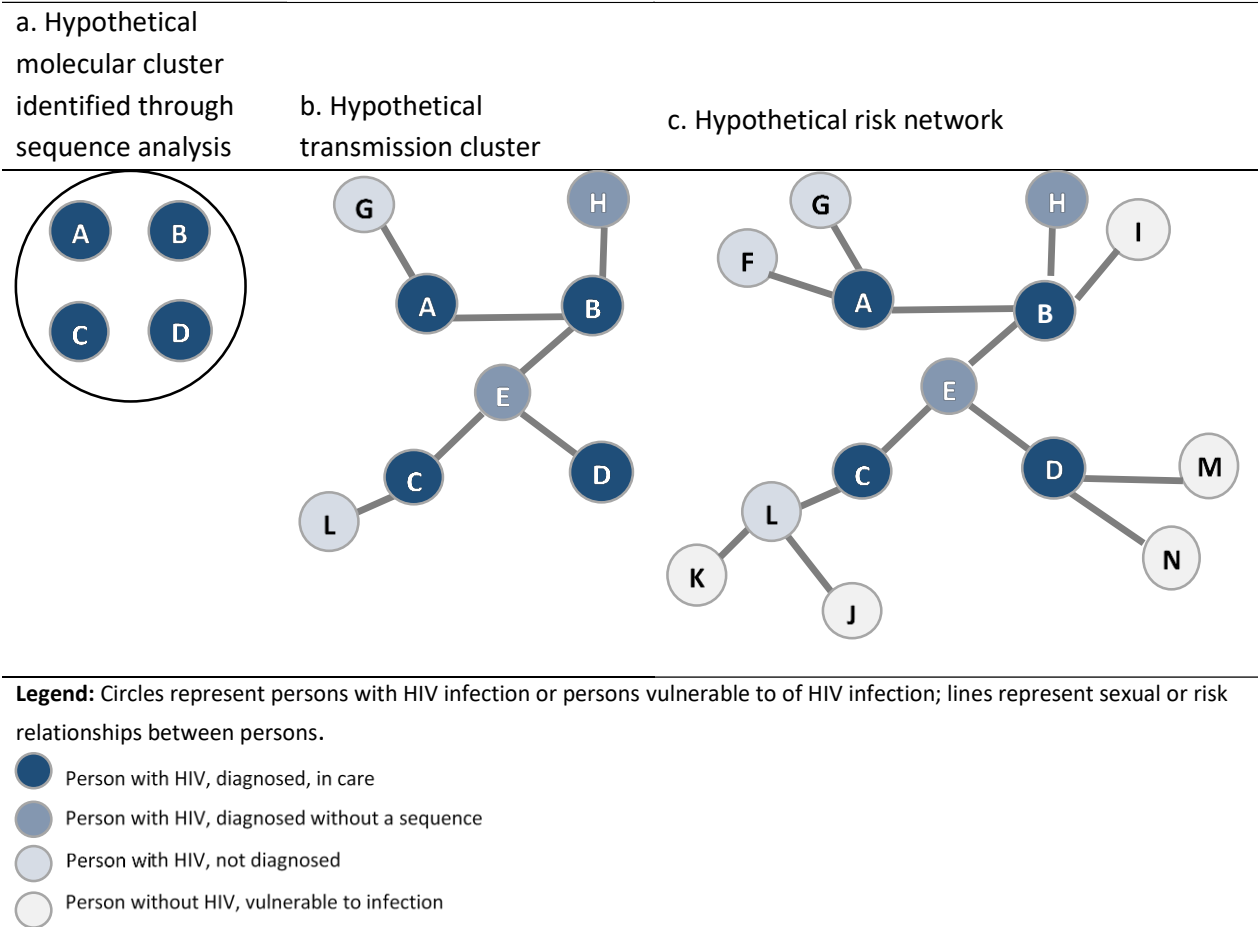
- In addition to the persons in the transmission cluster, the risk network will include:
  - Persons who are not HIV infected but are vulnerable to acquiring HIV

Figure 1-A. Molecular cluster and its transmission cluster and risk network.



- Molecular data cannot reveal which cases are directly related by transmission or determine the direction of transmission. This limitation is because two persons with genetically similar HIV strains are not necessarily directly linked by transmission: the relationship could be indirect, and there could be unidentified persons involved in transmission relationships.
- Use of molecular sequence data to identify molecular clusters is described in detail in the section [Cluster detection methods](#).
- Once a molecular cluster is identified, the corresponding transmission cluster and risk network can only be identified through investigation.

Figure 1-B. Hypothetical molecular cluster (a) and corresponding transmission cluster (b) and risk network (c).



### What is a time-space cluster, and how does it relate to a transmission cluster?

Analysis of case surveillance data to find **time-space clusters** provides another tool to identify transmission clusters. A **time-space cluster** occurs when the number of diagnoses of HIV infection in a particular geographic area exceeds levels expected given previous patterns. In some cases, time-space clusters may reflect one or more transmission clusters that have not yet been identified through molecular data or other approaches.

### Why are time-space clusters important?

Surveillance systems should systematically use all data and methods (time-space and molecular sequence-based approaches) available to detect clusters and outbreaks. Reported diagnoses, which are typically more timely and complete, can complement sequence-based techniques by detecting increases in diagnoses clustered in time and space. Routine use of this systematic method in near real time can automate detection of increases in HIV diagnoses that potentially merit further investigation and help state and local health departments prioritize and target HIV prevention efforts for maximal public health impact.

## Time-space and molecular cluster detection are complementary

	Time-space cluster detection	Molecular cluster detection
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Can be conducted in jurisdictions where sequence data are not yet available</li> <li>• May detect increases in diagnoses concentrated in time and space earlier than molecular clusters can</li> <li>• May detect increases in HIV diagnoses that are not due to a single transmission cluster but are nonetheless concerning</li> </ul>	<ul style="list-style-type: none"> <li>• Can identify transmission clusters that are not geographically concentrated</li> <li>• Can detect transmission clusters in geographic areas where HIV diagnoses overall are decreasing or stable</li> <li>• Correspond to transmission clusters</li> </ul>
<b>Limitations</b>	<ul style="list-style-type: none"> <li>• Clusters that are not concentrated geographically can be missed</li> <li>• Incremental increases in diagnoses across time may not generate an alert</li> <li>• In some jurisdictions, provisional surveillance data could result in observed increases that are later determined to be data artifacts</li> </ul>	<ul style="list-style-type: none"> <li>• May be less timely than time-space cluster detection</li> <li>• Detection limited based on incomplete data (i.e., sequences are only available for persons for whom a resistance test has been ordered, and for whom the test result has been reported to the health department)</li> </ul>

Time-space clusters may represent recent and ongoing HIV transmission. In some cases, time-space clusters may reflect transmission clusters that have not yet been identified through molecular data or other approaches. Time-space increases may indicate a single transmission cluster or multiple, smaller transmission clusters, both of which are important to investigate for prevention interventions. Increases in the number of diagnoses may also reflect an increase in HIV testing that has identified longstanding infections, which can also indicate a need for focused prevention efforts. Following the identification of time-space clusters, the review of additional data is important to determine whether investigations and interventions are needed.

For those time-space clusters that appear likely to represent recent and ongoing HIV transmission, steps should be taken to investigate and intervene by using many of the same principles that are outlined in the remainder of this document for molecular clusters.

Analysis of HIV surveillance data to identify time-space clusters can complement analysis of molecular data because time-space clusters can be detected in areas where collection of HIV nucleotide sequences is incomplete or delayed. Time-space cluster detection methods may be particularly useful for subgroups of HIV transmission that might warrant different investigative and intervention approaches because specific analyses can look at time-space clusters specifically among these groups. Notably, infections attributable to injection drug use (IDU) constitute a small proportion of total diagnoses, so the ability to identify potential IDU transmission clusters by analyzing IDU-attributable infections separately is a strength of this method.



# Purpose

## How can identifying transmission clusters help focus prevention efforts?

- Transmission clusters can identify risk networks that are concerning because of ongoing transmission, poor outcomes, or other reasons, such as transmission in a particularly vulnerable or underserved population, or transmission of drug resistance. Networks of concern include:
  - *Networks in which HIV transmission occurred rapidly* (with multiple new infections occurring within months of one another) and within a recent time window (within ~1–2 years). Recent rapid transmission suggests extremely high-risk transmission networks and could represent an ongoing outbreak; public health intervention could interrupt transmission and prevent future infections.
  - *Networks with characteristics suggesting high potential for ongoing transmission*, such as identification of risk behaviors, including IDU or coinfection with STDs or hepatitis.
  - *Networks characterized by poor outcomes*, such as late diagnosis, lack of viral suppression, or coinfection with STDs, hepatitis, or other comorbidities; this could suggest poor access to care and could indicate a network in which persons with HIV infection not yet diagnosed are contributing to ongoing transmission.
  - *Networks representing vulnerable or underserved populations*, such as pregnant women, adolescents, rural populations, persons who inject drugs (PWID), foreign-born persons, or other groups defined by local epidemiology and context.
  - *Networks in which drug-resistant strains of HIV are being transmitted*, particularly networks with resistance to preexposure prophylaxis (PrEP) regimens.
  - *Networks not reached by testing efforts*, as evidenced by large proportions of infections that were diagnosed through incidental testing, such as screening in plasma centers, emergency departments, or correctional institutions; this could indicate other infections in the network that have not yet been diagnosed and are contributing to ongoing transmission.
- Investigation of transmission clusters can identify key characteristics of the risk network to guide intervention efforts to improve outcomes and prevent additional infections.
  - Investigation includes the examination of existing data, including partner services data, or collection of new data to identify factors associated with transmission
- Intervening in risk networks can improve outcomes; activities that interrupt transmission include:
  - Identifying persons with diagnosed HIV infection in the transmission cluster who are out of care, and ensuring that these persons are linked to or re-engaged in care
  - Identifying persons with undiagnosed infection who are part of the transmission cluster, and linking these persons to care
  - Identifying persons without HIV infection in the risk network who are vulnerable to acquiring HIV and offering effective prevention interventions, such as PrEP
  - Interventions at the transmission cluster or population-level to address social-structural or programmatic factors that contributed to transmission (for example, investigation of a transmission cluster could lead to the recognition of gaps in existing prevention programs)
- By expanding our knowledge of transmission dynamics, transmission cluster data can be a powerful tool to help target the interventions we know are effective (engagement in care, HIV testing, PrEP).

## HIV sequence reporting

### How are molecular sequence data generated and collected?

#### Generation of molecular sequences

- Molecular sequences are generated through drug-resistance testing.
- Drug-resistance testing is conducted to identify mutations associated with viral resistance to antiretroviral medications and to help the HIV care provider select an appropriate treatment regimen. This testing is recommended for all persons with diagnosed HIV infection and should be conducted at entry to HIV care.
- Drug-resistance testing is typically ordered by providers at entry to HIV care, but can also be ordered at a later time (for example, if a patient is on treatment but does not have a suppressed viral load).
- The final output of drug-resistance testing is a report identifying known mutations that confer drug resistance, which is sent to the care provider. The HIV molecular sequence is generated as a part of the testing process, and laboratories can retrieve this information for surveillance reporting purposes. Current testing methods generate sequences by using a sequencing method called Sanger sequencing.

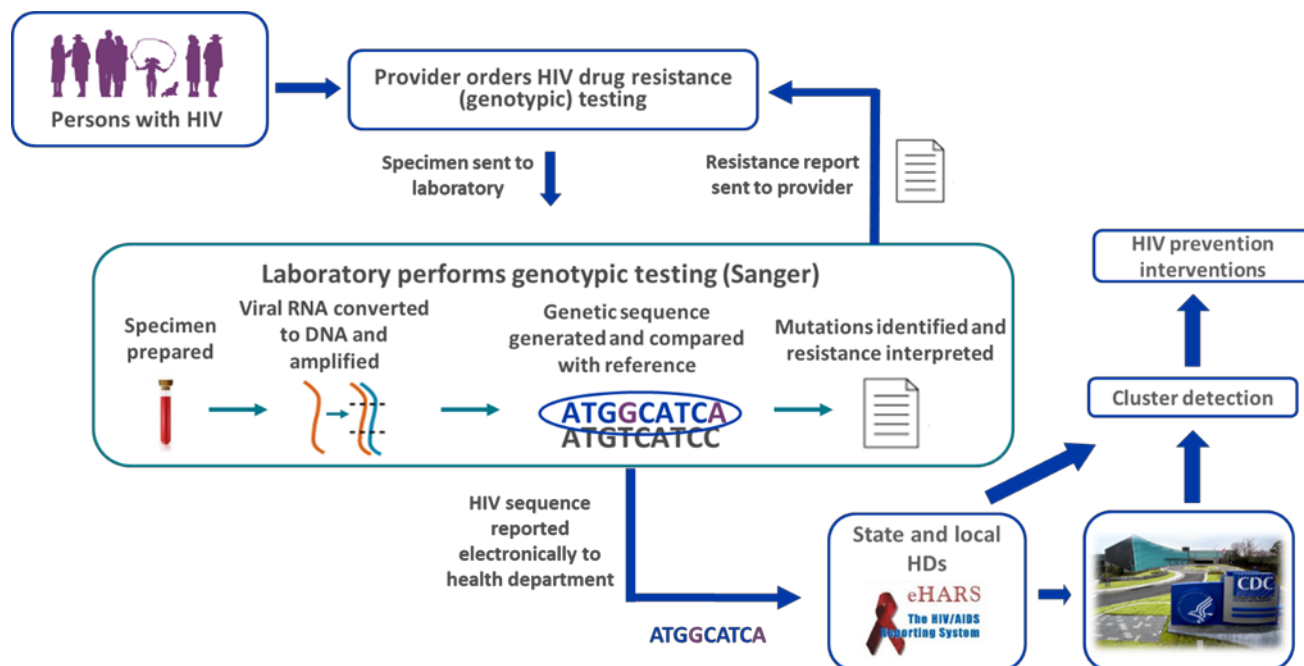
#### Collection of molecular sequence data

- Laboratories report HIV molecular sequence data to HIV surveillance jurisdictions; these data are an integrated component of the National HIV Surveillance System in all jurisdictions.
- Health departments report all HIV case information collected by HIV surveillance to CDC (demographics, transmission category, CD4 results, viral load results, HIV molecular sequence) without identifying information (name, street address). See Figure 3-A.
- Collection of HIV sequence data is monitored as part of the National HIV Surveillance System; the goal for sequence reporting is  $\geq 60\%$  of persons with diagnosed HIV infection. Achieving high sequence reporting completeness is essential in order to detect clusters and to capture the greatest extent of molecularly linked cases in a cluster. Jurisdictions should refer to the process and outcome standards listed in the Technical Guidance File *Evaluation and Data Quality*.
- For more information on nucleotide sequence reporting, see Technical Guidance File *Reporting*.

**Outcome standard:** Of all persons with HIV infection diagnosed during the evaluation year, at least ( $\geq$ ) 60% have an analyzable nucleotide sequence, assessed 12 months after the evaluation year

Jurisdictions are should achieve molecular HIV sequence reporting of  $\geq 60\%$  of persons with diagnosed HIV infection each year. Achieving high sequence reporting completeness is essential in order to detect clusters and to capture the greatest extent of molecularly linked cases in a cluster.

**Figure 3-A. Collection of HIV molecular sequence data**



#### Limitations in molecular sequence data

- Although drug-resistance testing is recommended for all persons with diagnosed HIV infection, not all persons receive a drug-resistance test.
- In some instances, even if a drug-resistance test is completed, reporting challenges prevent a health department from receiving a molecular sequence for a person.
  - For example, in some jurisdictions, sequences may not be reported for persons receiving medical care in federal systems (e.g., Veterans Affairs or federal prisons) or those in blinded clinical trials.
  - In some cases, the identifying and locating information provided by the laboratory could be so incomplete that the sequence cannot be linked to a person in the surveillance data.

## Expanded Guidance on Collection, Use and Release of HIV Sequence Data

### Summary

- State and local HIV surveillance programs funded by CDC should collect HIV sequence data only in the form of Sanger sequences or, when next generation sequencing (NGS) has been conducted, consensus sequences. Currently, there is no documented public health benefit to collecting raw NGS data through HIV surveillance, and therefore, the risks of collecting these data outweigh any potential benefits.
- Analyses of HIV sequence data reported to HIV surveillance programs should not be interpreted as determining transmission direction or proving direct transmission between individuals, nor should analyses attempt to do so.
- CDC does not release HIV sequence data reported from HIV surveillance programs to GenBank or other publicly available sequence data repositories. State and local HIV surveillance programs funded by CDC and their academic partners should not release sequence data to GenBank or other publicly available sequence repositories without individual consent.

### Reporting considerations related to next generation sequencing

Collecting HIV sequence data is important for detecting and responding to HIV clusters and outbreaks. The sequences typically used for cluster detection by CDC and state and local health departments are either generated through Sanger sequencing or are consensus sequences generated after next generation sequencing (NGS). These sequences provide the most common nucleotide at each location in the sequenced gene(s) and do not provide the ability to identify direction of transmission. These data provide the necessary information to detect HIV clusters and outbreaks and respond with prevention and care interventions, which is the intended purpose for the collection of these data. Raw NGS HIV sequence data (i.e., the granular information about the sequence of each of the thousands of viruses in a person) may offer additional potential to infer direction of transmission between individuals, which is not the intended purpose of collecting these data. The collection of raw NGS data by HIV public health surveillance systems carries implications for the ethical balance of risks and harms of molecular sequence collection.

Currently, the risks of collecting raw NGS HIV data outweigh any potential benefits, as there is no documented public health benefit to collecting these data and these data may offer additional potential to infer direction of transmission. Perceived or actual ability to infer the direction of transmission could be associated with additional risks, such as release of data for non-public health purposes (i.e., for use in criminal or civil cases) or use of data to prompt public health actions that stigmatize people with HIV or

people experiencing marginalizing circumstances. These factors could undermine community trust in this work.

**Therefore, when laboratories conduct NGS, only HIV consensus sequences (and not raw NGS sequence data) should be reported to or collected by CDC-funded HIV surveillance programs.**

Modernization of public health surveillance systems is important and should allow for flexibility in future needs, but raw NGS HIV data should not be collected in public health data systems at the current time. Continued reassessment of the relative benefits and risks of collecting these data, with guidance and input from key partners, including health departments, people with HIV, and laboratories, is essential to understand changing conditions that might shift the balance of benefit and risk. Conditions that might warrant reconsideration of the collection of NGS sequence data by public health agencies include: evidence demonstrating an established public health benefit to the collection and use of these data; people with HIV no longer experiencing disproportionate stigma or harms from criminal justice systems; community consultations to meaningfully involve people with HIV in this decision; and adequate protections in all jurisdictions that collect these data that ensure the data are used only for public health purposes by prohibiting data from being released or used as evidence in criminal or civil litigation.

#### Directionality of transmission

**Moreover, analyses of HIV sequence data reported to HIV surveillance programs, whether conducted by health departments or academic partners, should not be interpreted as determining transmission direction or proving direct transmission, nor should analyses attempt to do so.** Rare exceptions might be considered (for example, when needed to establish or exclude an unusual route of transmission or when individual consent has been provided).

#### GenBank and other public repositories

CDC does not release HIV sequence data reported from HIV surveillance programs to GenBank or other public repositories. Existing CDC guidance states that CDC-funded jurisdictions should not release identifiable, individual-level data to anyone outside of public health except in circumstances involving significant risk of harm to the public or if required by law. Even when required, only the minimum information should be released. **Therefore, HIV sequence data reported to CDC-funded HIV surveillance programs should not be released to GenBank or other public repositories by health departments**

# Cluster detection methods

## Identifying growing transmission clusters by using surveillance data

Routine analyses of surveillance data can identify growing transmission clusters that would otherwise not be identified. Transmission clusters can be identified both through molecular and time-space clusters, and surveillance systems should systematically use all data and methods (time-space and molecular sequence-based approaches) available to detect clusters and outbreaks.

### How are molecular clusters identified?

#### HIV is constantly evolving

- The molecular sequence (also called nucleotide sequence) of HIV accumulates changes over time. Immediately following transmission of HIV between two people, the molecular sequence of the HIV strain in the recipient will be nearly identical to strains found in the transmitting person. As time passes, however, the strains infecting each person will change independently of one another and will look more and more different. In each new person infected, the virus will continue to change independently, so the HIV strains will look less and less similar over the course of a transmission chain. This relationship between the extent of the difference and the relatedness of strains is sometimes referred to as a “molecular clock.” For more detail about the evolution of HIV, including the rate of change, please see [Appendix B](#) and [Appendix C](#).
- Analysis of the molecular sequence of viral strains can determine how genetically similar the strains are.

Persons infected with viral strains that are genetically similar may be closely related (directly or indirectly) via transmission.

#### Analysis of sequence data

- Many approaches are available for analyzing HIV sequence data, but the current approach used by CDC that should also be used by state and local health departments is transmission network analysis. In this analysis, each HIV molecular sequence is compared to every other HIV molecular sequence to identify pairs of sequences that are extremely similar (i.e., sequences that have a very small genetic distance, or difference). The level of genetic similarity used to identify closely related pairs is referred to as the **genetic distance threshold**.
  - The genetic distance threshold applied can vary based on the goal of the analysis. For example, to identify cases related by recent and rapid transmission, a very close genetic distance threshold can be used—for example, 0.5% (which corresponds to 5 different nucleotides in a sequence that is 1,000 nucleotides long). A genetic threshold of 0.5% corresponds approximately to 2–3 years of viral evolution separating these strains (which may correspond to time since a common transmission event). By contrast, if the goal is to identify all possible cases that could be related to a given case, a larger genetic distance threshold can be used—for example, 1.5%. A 1.5% threshold corresponds approximately to 7–8 years of viral evolution separating these strains.
- Pairs of infections with similar sequences are then connected with one another to construct transmission networks and identify clusters of very closely related cases.

- Lines are drawn between each pair of closely related sequences. This creates clusters that may have as few as two connected sequences, but can contain many more sequences that are connected.
- Although data on potential transmission linkages between persons (i.e., pairs of people with infections that have genetically linked sequences) are useful in constructing molecular clusters, these data may be subject to misinterpretation by those not familiar with this type of analysis. As a result, CDC recommends minimizing use of these data and instead focusing on cluster-level data (i.e., considering all people in a cluster for intervention rather than focusing on people based on their position in the cluster). CDC does not recommend disseminating genetic network diagrams beyond the group of staff involved in the analysis of sequence data.

**Limitations of and considerations for visualizing networks based on genetic data**

Importantly, although some tools, such as Secure HIV-TRACE and MicrobeTrace, generate network diagrams of clusters based on genetic distance data, there are important limitations to drawing inferences from these data at an individual level. Although two persons infected with highly similar HIV strains could be directly linked through transmission, other transmission relationships could be consistent with this sequence similarity: both could have been infected from a third source, or they could be connected indirectly through a transmission chain including 1 or more intermediaries. Because of this scientific uncertainty, the potential for the misuse and misinterpretation of these data presents a concern. Moreover, presence of or patterns of linkages can be affected by timing of diagnoses and drug-resistance testing. Although analysis of molecular data to identify growing transmission clusters can identify important opportunities for individual- and cluster-level public health interventions, inferences about specific transmission linkages or indirect inferences about sexual or other risk behaviors should not be used to guide services or follow-up at the individual level. Because of the potential for misinterpretation of these diagrams, **it is not recommend to disseminate genetic network diagrams beyond the group of staff involved in the analysis of sequence data.**

- The period of data included in the analysis may vary depending upon the goals. CDC recommends that analyses focused on identifying clusters that represent recent HIV transmission include only sequences from infections diagnosed in recent years (e.g., the 3 most recent years); this entails restricting data to the most recent 3 years of diagnoses prior to analysis in Secure HIV-TRACE (HIV TRAnsmiSSion Cluster Engine).
  - Using a shorter period, such as 3 years, can identify bursts of recently infected cases that indicate recent and potentially ongoing transmission. Although persons with diagnoses outside of the time window who are out of care could be sources of ongoing transmission, limiting the time window allows the analysis to flag clusters with substantial recent growth. A secondary analysis can then be conducted to identify additional potentially related persons with HIV who might be considered in the investigation.
  - Analysis conducted for other purposes, such as understanding a larger transmission network, might include cases diagnosed over a much longer period.
- For details about HIV sequence data analysis, including the selection of the genetic distance threshold to define a cluster, a description of the regions of the HIV genome included in the analysis, and other technical details, please see [Appendix B](#) and [Appendix C](#).



## How can jurisdictions identify molecular clusters?

- Analysis of molecular sequence data by state and local HIV surveillance programs can allow for identification of clusters in closer to real time and for monitoring of clusters that have been previously identified. Barriers to reporting and processing of HIV sequences to allow prompt identification of growing clusters should be addressed.
- Secure HIV-TRACE (supported by CDC, University of California, San Diego, and Temple University) is a bioinformatics tool that allows HIV surveillance programs to detect, analyze, and visualize clusters. This tool is available to jurisdictions to conduct analyses locally.
  - HIV surveillance programs should analyze their data by using Secure HIV-TRACE at least monthly.
    - HIV surveillance programs can obtain additional information and technical assistance related to Secure HIV-TRACE by emailing [hivtrace@ucsd.edu](mailto:hivtrace@ucsd.edu).
  - Separately funded city/county HIV surveillance programs should collaborate with their respective state health department to develop standard analysis protocols (i.e., to determine if and when data will be analyzed separately or jointly).
  - An enhancement to facilitate the identification of multijurisdictional clusters in Secure HIV-TRACE is currently in development. CDC will routinely analyze national data to identify clusters that involve cases from multiple jurisdictions.
- When partnering with external collaborators (e.g., academic institutions) to analyze sequence data to identify clusters, ensure that the jurisdiction's protocols consider key factors, including data sharing and security and confidentiality of HIV-related information. Such collaborations should have a legitimate public health purpose and support the jurisdiction's HIV prevention efforts, use de-identified data if data are shared, and involve the minimum amount of information necessary. It is recommended that the parameters of such collaborations be outlined in a written project plan or agreement (e.g., a data use agreement [DUA], memoranda of agreement [MOA], memoranda of understanding [MOU], or business contract if applicable). Agreements should include a description of the project and goals, methods, data elements, access and storage requirements, roles and responsibilities, confidentiality and security provisions, disposition of the data, and a description of the dissemination plan or products. Some collaborations determined to be nonresearch or exempt from Institutional Review Board (IRB) review should still be approved by the jurisdiction's Overall Responsible Party (ORP) and may benefit from an additional review and vetting by a standing data analysis review group or public health advisory group (e.g., community planning group or advisory board) or ad hoc review group. Determining whether proposed data sharing with an academic institution supports public health and a jurisdiction's HIV prevention efforts often involves ethical and legal questions. Consulting with an autonomous body of persons experienced in public health ethics may provide insight and feedback on proposed activities.
- Any use of sequence data for research purposes must be carefully considered, be approved by the jurisdiction's ORP, and be subject to IRB approval as appropriate. Any use of identifiable surveillance data as part of any research is contingent on a clearly stated public health purpose, a demonstrated need for identifiable data, IRB and ORP approval, and the signing of a confidentiality agreement regarding rules of access and final disposition of the data and plans for dissemination or publication of results. Depending on the amount and type of data requested, the use of nonidentifiable data for research is generally permissible but because of the sensitive nature of cluster analyses, IRB approval is recommended and may be required. For more information, see [Data Security and](#)



## **How can decisions in the analysis to identify molecular clusters impact cluster prioritization?**

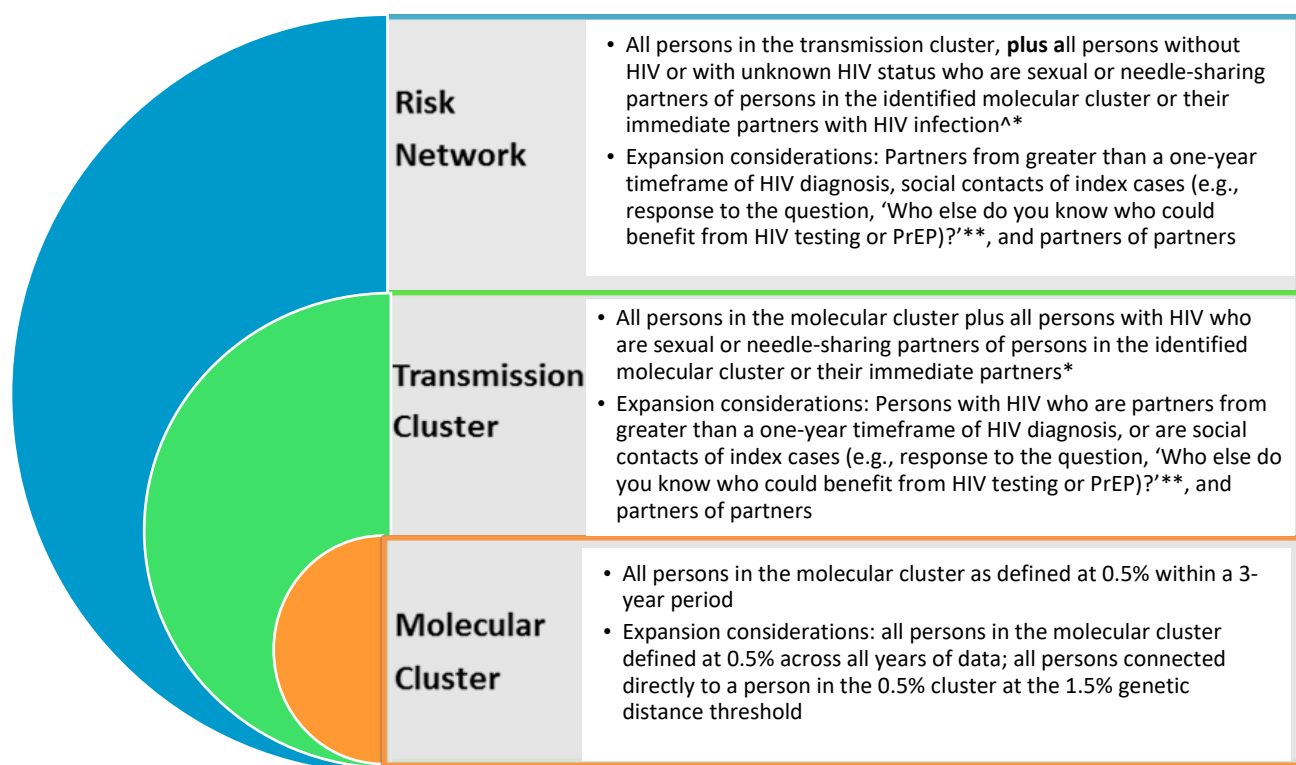
Key decisions in the analyses to identify clusters can have a large impact on the number and composition of clusters identified. For example, analysis using a larger genetic distance threshold (e.g., 1.5%) can identify clusters where some or all transmissions occurred in the more distant past, and where transmission connections between cases are more likely to be indirect; these clusters would likely include more persons and be more intensive to investigate. Additionally, analysis conducted by using datasets that include cases diagnosed over many years may result in the identification of large, complex clusters comprised of many independent transmission chains, where investigation and intervention could be challenging. In general, to focus on recent and rapid transmission, we recommend using a smaller genetic distance threshold (0.5%) to identify clusters of persons with infections that are more closely temporally linked, and limiting analyses to cases diagnosed in the most recent 3-year period. CDC's criteria to identify priority clusters includes a 0.5% genetic distance threshold and the most recent 3-year period of data. Analyses of national data demonstrate the importance of these restrictions in focusing detection on clusters that represent recent and rapid transmission<sup>1</sup>.

After a cluster that represents recent and rapid transmission has been identified, the definition of that molecular cluster can be expanded to be more inclusive and to identify other persons who might be related to this cluster. An expanded molecular cluster definition can, for example, capture persons who are likely closely connected to the transmission cluster, but whose sequence, while related, does not meet the 0.5% genetic distance threshold. Figure 3-B offers considerations for expanded definitions of the molecular cluster, transmission cluster, and risk network.

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<sup>1</sup> Oster AM, France AM, Panneer N, Bañez Ocfemia MC, Campbell E, Dasgupta S, Switzer WM, Wertheim JO, Hernandez AL. Identifying clusters of recent and rapid HIV transmission through analysis of molecular surveillance data. *J Acquir Immune Defic Syndr* 2018. doi:10.1097/QAI.0000000000001856.

**Figure 3-B. Suggested definitions for molecular clusters, transmission clusters, and risk networks, with considerations for expansion.**



<sup>\*</sup>Identified as partners within a 1-year timeframe of HIV diagnosis, or at any time following HIV diagnosis during which the index case was not virally suppressed.

<sup>\*\*</sup> Note that in some cases, people with HIV who are partners identified through partner services might have discordant molecular sequences. For purposes of public health response, these persons should still be included in the transmission cluster.

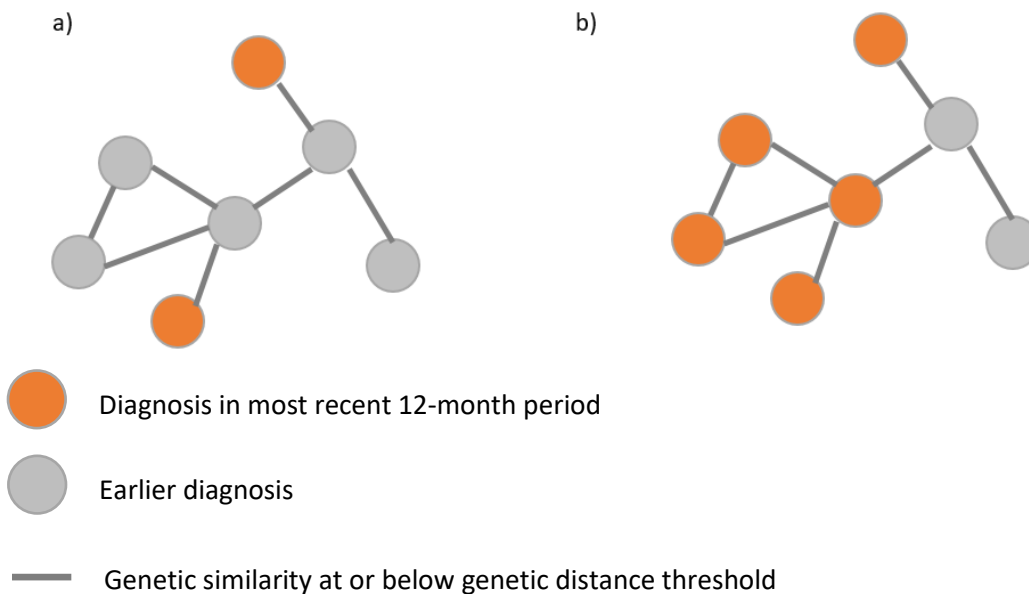
<sup>^\*</sup>Note that the risk network will include all claimed partners, even if these persons were not named, did not have sufficient information to initiate contact, or cannot be located.

## How does CDC identify molecular clusters?

- CDC conducts routine analyses to identify clusters that are concerning for recent and rapid transmission of HIV. CDC analyses will not be as timely as local analyses, because of the timeline for submission of data to CDC and data processing prior to the data becoming available for analysis. For clusters detected by the jurisdiction, CDC analyses may detect additional members from other jurisdictions, and in some cases CDC analyses will detect clusters that were not detected by any jurisdiction.
- Analyses are conducted by using national data that are available each quarter (based on data transmitted by HIV surveillance jurisdictions to CDC in March, June, September, and December).
- Prior to analysis, all HIV sequences in the national dataset are evaluated to determine the quality of the data and to remove potential contaminants. Only sequences that include protease or reverse transcriptase regions of the HIV genome and are of sufficient length are included in the analysis.
- CDC analyzes data by using a secure, local installation of HIV-TRACE, a software tool developed by University of California, San Diego and Temple University.

- With the goal of identifying clusters consistent with recent and rapid HIV transmission, these analyses include only cases diagnosed in the most recent 3-year period, and use a genetic distance threshold of 0.5%.
- National priority clusters are defined based on the burden of HIV in the jurisdiction. For lower burden jurisdictions (defined by membership in CDC’s low-burden jurisdiction workgroup), priority clusters are defined as clusters with at least 3 cases diagnosed within the most recent 12-month period. For all other jurisdictions, priority clusters are defined as those with at least 5 cases diagnosed within the most recent 12-month period. Many clusters cross jurisdictional boundaries; in these cases, the priority cluster determination is made based on the number of cases diagnosed in the cluster overall, regardless of jurisdiction.
- When a cluster of concern is identified, the primary jurisdiction (the jurisdiction with the majority of cases in a cluster) is notified and a cluster snapshot or line list describing the cluster is transmitted securely via SAMS. This cluster snapshot or line list will include case count information for all cases in the cluster, regardless of jurisdiction, but will only include line-listed information for persons in the primary jurisdiction unless a specific data sharing agreement between the jurisdictions involved and CDC allows this information to be shared. A cluster snapshot companion document, showing the elements included in a cluster snapshot, can be found in [Appendix D](#). Jurisdictions that are notified that they have persons involved in a cluster but are not the primary jurisdiction will have access to the statuses of their cases in the cluster through CDC, however the mechanism for routinely sharing this information is still being determined.
- CDC’s prioritization criteria may be modified and expanded in the future, as capacity allows.

**Figure 3-C. Examples of clusters that would not (a) and would (b) meet national priority criteria.**

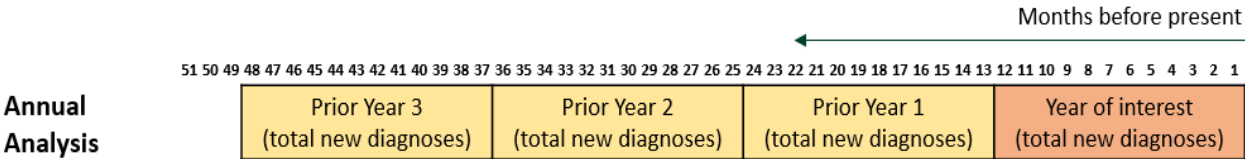


### How are time-space clusters identified?

- CDC, with input from some jurisdictions who conduct this type of routine analysis, has developed methods for analysis of surveillance data to detect unusual increases or changes in normal HIV diagnosis and reporting patterns.
- Jurisdictions should conduct time-space analysis locally, at least monthly.

- CDC provides a SAS program that jurisdictions can use to conduct time-space analysis at the local level. Jurisdictions may choose to use the CDC-provided SAS program, adapt it for their local purposes, or develop other approaches to identifying time-space clusters. The CDC SAS program implements the current approach:
  - Define the period of interest for analysis as the most recent 12 months of HIV diagnosis (e.g. Jan 2017–Dec 2017).
  - Define the comparison group as the previous 36 months (e.g. Jan 2014–Dec 2016).
  - Define the geographic area of interest. At a minimum, this should include the state and each county within the state. Other geographic areas of interest may include regions within the state, metropolitan statistical areas, etc.
  - Populations for time-space analysis:
    - Time-space analyses can be conducted for all diagnoses or for specific risk groups. CDC recommends that, at a minimum, jurisdictions conduct time-space analyses for:
      - Overall diagnoses
      - Diagnoses among PWID
        - Note that these analyses could be conducted for IDU only, MSM-IDU only, or IDU + MSM-IDU
      - Analyses could also be conducted for other populations with risk factors for HIV infection. Note that analyses of diagnoses among MSM could be with or without MSM-IDU.
- Performing time-space analysis with the CDC-provided SAS program requires the following steps:
  - Calculate the HIV case counts for each county (or other relevant geographic area) for the most recent 12 months (or other period of interest). Jurisdictions must also calculate the average HIV case counts per year for the same areas for the previous 36 months.
  - Calculate the standard deviation for the mean number of cases during the 36-month comparison group.
  - Construct an interval of 2 standard deviations around the mean.
  - Compare the results to the most recent 12 months of data. The CDC-provided SAS code creates an “alert” for case counts that fall more than two standard deviations above the mean, as well as an increase of more than 2 diagnoses over the baseline. Jurisdictions may add additional, more stringent criteria in defining geographic and time windows to suit their needs.
- Although the primary responsibility for time-space analysis is with jurisdictions, CDC will also routinely conduct these analyses to identify clusters crossing jurisdictions.
- For very low morbidity jurisdictions, a routine manual review of data to identify increases, rather than an analytic approach, may be sufficient.

**Figure 3-D. Example of analysis to identify time-space clusters, comparing number of diagnoses in the most recent 12-month period to 36-month baseline**



### Next steps once a cluster has been identified

Identifying transmission clusters is an important first step that should be followed by investigation and response to interrupt the spread of HIV. CDC has developed additional guidance tools and resources to assist jurisdictions with additional steps in this process; see [CDC’s HIV cluster and outbreak detection and response homepage](#).

## Outcome measures related to cluster detection

PS 18-1802 includes outcome standards related to sequence reporting, cluster detection, and cluster response. The outcome standard for nucleotide sequence reporting is described in the Technical Guidance File *Evaluation and Data Quality*. The outcome standard related to cluster detection is described below. Additional outcome standards related to cluster response can be found in the PS18-1802 EPMP, under Strategy 3.

**Measure 3.1.1:** Analyze surveillance and other data using CDC-recommended approaches at least monthly to identify HIV transmission clusters and outbreaks.

**Description:** Local jurisdictions must use secure HIV-TRACE or other CDC-recommended approaches to conduct molecular analysis of HIV sequence data at least monthly, provided new data are available on a monthly basis. (For jurisdictions that have not collected HIV sequence data prior to PS18-1802, analysis of sequence data must occur once sequence data begin to be collected.) It is also required that jurisdictions analyze HIV case surveillance data monthly to identify time-space clusters in HIV diagnoses. This is an activity that can begin in all jurisdictions, including those that do not yet have molecular sequence data available. Analysis results of both molecular and time-space clusters will be used to identify new transmission clusters and to monitor the growth of existing clusters.

City-level jurisdictions may defer to the state to run this analysis monthly, as long as an agreement is in place between both parties. City-level jurisdictions must work with the state to ensure timely reporting of identified clusters and to develop plans for investigation.

**Target:** N/A

**Data to be reported:**

- Timing of analyses (when analyses were conducted)
- Type of analysis conducted (molecular and/or time-space)

**Methods of Reporting Data:** Jurisdictions will use the SER to report whether the analyses were conducted. Secure HIV-TRACE reports will be used to confirm the information provided in the SER.

## Appendix A: List of abbreviations and key definitions

<b>Cluster snapshot</b>	A document developed by the CDC HIV Incidence and Case Surveillance Branch to communicate cluster and case-level data on a molecular cluster to state and local health departments.
<b>Disease intervention specialists (DIS)</b>	Health department personnel who are specifically trained to provide partner services. Some health departments use different titles for persons providing partner services. In addition, in certain jurisdictions, other persons (e.g., HIV counselors or clinicians) either inside or outside of the health department provide certain or all elements of partner services.
<b>Drug-resistance testing</b>	Conducted in order to identify mutations associated with viral resistance to antiretroviral medications and help the HIV care provider select an appropriate treatment regimen. Drug-resistance testing is recommended for all persons with diagnosed HIV infection, with the recommendation that testing be conducted at entry to HIV care. Drug-resistance testing is typically ordered by providers at entry to HIV care, but can also be ordered at later time points (for example, if a patient is on treatment but does not have a suppressed viral load). A nucleotide sequence is generated as an intermediate byproduct from a drug-resistance test.
<b>Engagement in care</b>	Measured by whether a person with diagnosed HIV infection has had at least one HIV medical care visit during the analysis period
<b>Genetic distance threshold</b>	The level of genetic similarity used to identify closely related pairs of sequences. The genetic distance threshold used can vary based on the goal of the analysis.
<b>HIV TRAnsmiSSion Cluster Engine (HIV-TRACE)</b>	A bioinformatics tool developed by researchers at the University of California, San Diego to analyze nucleotide sequences and identify clusters representing recent and rapid transmission. A secure local installation of HIV-TRACE at CDC is used to run routine analyses on national surveillance datasets.
<b>Molecular cluster</b>	Identified through analysis of HIV genetic sequence data that is generated through HIV drug-resistance testing. Molecular clusters contain only those people for whom molecular data is available and can be analyzed, and contains a subset of what is likely a larger transmission cluster
<b>Molecular data</b>	See “Nucleotide sequence”

<b>Multijurisdictional cluster</b>	A cluster in which coordination across jurisdictions is required for effective investigation and response. Often, multijurisdictional clusters will include cases reported from multiple states, however the jurisdictional issues involved could be relevant for clusters involving multiple counties within a single state, particularly if they include separately funded HIV surveillance or prevention programs.
<b>National HIV Surveillance System (NHSS)</b>	The primary source for monitoring HIV trends in the United States. The primary functions of the National HIV Surveillance System (NHSS) are (1) to provide accurate epidemiologic data to monitor the incidence and prevalence of HIV infection and HIV-related morbidity and mortality and (2) to use these data trends to assist in public health planning and policy. CDC provides federal funding to states and territories through surveillance cooperative agreements to achieve the goals of NHSS and also to assist states in developing their own surveillance programs in accordance with state and local laws and practices.
<b>National priority cluster</b>	A molecular cluster that has met certain criteria and which should be flagged for preliminary investigation. Currently, CDC-defined national priority clusters for high and medium morbidity jurisdictions are clusters identified at a 0.5% genetic distance threshold with $\geq 5$ cases in the most recent 12-month period. For low morbidity jurisdictions, CDC-defined priority clusters are those identified at a 0.5% genetic distance threshold with $\geq 3$ cases in the most recent 12-month period. Analyses of clusters meeting the abovementioned criteria indicates similar transmission rates that are approximately 11 times that of the transmission rate among HIV infected individuals in the US. In addition to using criteria for CDC-defined priority clusters, jurisdictions may also develop criteria to identify additional, locally defined priority clusters.
<b>Nucleotide sequence</b>	An intermediate byproduct of an HIV drug-resistance test. Analysis of nucleotide sequences can identify pairs of sequences that are extremely similar and which may be closely related in transmission
<b>Partner services</b>	A broad array of services that should be offered to persons with HIV infection, syphilis, gonorrhea, or chlamydial infection and their partners. A critical function of partner services is partner notification, a process through which infected persons are interviewed to elicit information about their partners, who can then be confidentially notified of their possible exposure or potential risk. Other functions of partner services include prevention counseling, testing for HIV and other types of STDs (not necessarily limited to syphilis, gonorrhea, and chlamydial infection), hepatitis screening and vaccination, treatment or linkage to medical care, linkage or referral to other prevention services, and linkage or referral to other services (e.g., reproductive health services, prenatal care, substance abuse treatment, social support, housing assistance, legal services, and mental health services).
<b>Preexposure prophylaxis (PrEP)</b>	A way for people who do not have HIV but who are at substantial risk of getting it to prevent HIV infection by taking a pill every day
<b>Primary jurisdiction</b>	The jurisdiction with the majority of cases in a molecular cluster

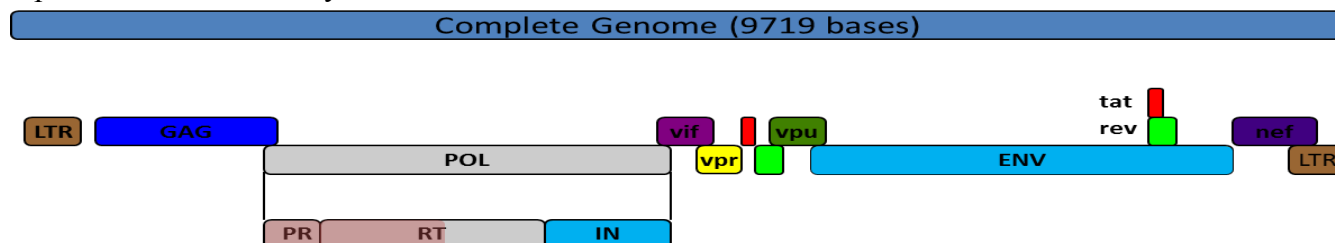
<b>PWID</b>	Persons who inject drugs
<b>Risk network</b>	Includes the group of persons among which HIV transmission has occurred and could be ongoing. This network includes persons who are not infected with HIV but may be vulnerable to infection, as well as the persons with HIV in the transmission cluster
<b>Secure HIV-TRACE</b>	A web-based bioinformatics tool developed by researchers at the University of California, San Diego and Temple University to analyze HIV nucleotide sequences and identify molecular clusters. Secure HIV-TRACE is available to individual public health institutions to facilitate real-time analysis by state and local health departments to better understand and respond to their specific HIV burden.
<b>Time-space cluster</b>	A time-space cluster occurs when the number of diagnoses of HIV infection in a particular geographic area is elevated above levels expected given previous patterns.
<b>Transmission cluster</b>	A group of persons with HIV who are connected by HIV transmission. A transmission cluster represents a subset of a risk network



## Appendix B. HIV Molecular Evolution

### HIV-1 Genome and Structure

The HIV-1 RNA genome is comprised of approximately 10,000 nucleotides that are the code for 9 to 10 genes that encode for 16 proteins. Tgroup specific antigen (*gag*), polymerase (*pol*) and envelope (*env*) genes encode the information needed to make the structural proteins for new viral particles. The *pol* gene also codes for enzymes for viral replication (reverse transcriptase [RT]) and integration into the host genome (integrase [IN]). The other genes encode for regulatory or accessory proteins that control replication and infectivity.



### HIV-1 Genetic Evolution

HIV-1 replicates rapidly, generating about 10 billion viral particles every day in an untreated person. HIV-1 also has a high genomic evolutionary rate ranging from  $1.3 \times 10^{-3}$  to  $3.5 \times 10^{-3}$  nucleotide substitutions/site/year depending on the HIV-1 subtype and specific gene region examined. For *pol*, this corresponds to a rate of evolution of 1% every 10 years. The genetic distance that reflects the relative change between HIV sequences can be used as a proxy for the number of years since the HIV sequences diverged from a common ancestor or transmission event. The genetic distance applied can vary based on the goal of the analysis. For example, to identify cases related by recent and rapid transmission, a very close genetic distance threshold should be used—for example, 0.5% (which, for a sequence that is 1000 nucleotides long, corresponds approximately to 5 different nucleotides). A genetic threshold of 0.5% corresponds to approximately a maximum of 5 years of viral evolution (2–3 years for each person, because the virus is evolving in each person) separating these strains (which may correspond to time since a common transmission event). By contrast, if the goal is to identify all possible cases that could be related to a given case, a larger genetic distance threshold should be used—for example, 1.5%. A 1.5% threshold corresponds to a maximum of 15 years of viral evolution separating these strains.

The high substitution rate is believed to be caused by the low fidelity of the RT enzyme during replication and by HIV-1 genome interactions with other cellular enzymes. RT is the enzyme used by HIV to convert single-stranded HIV RNA into double-stranded cDNA allowing integration into the host genome. Because RT does not have a proofreading mechanism, transcription from viral RNA to DNA is error prone. HIV's fast replication cycle and high substitution rate of HIV-1 leads to high genetic diversity, which enables the virus to evade the immune system and to develop drug-resistant mutations.

Mutations have been found in all HIV-1 genes. When considering only the *pol*, *gag*, and *env* genes, there are small sequence regions in each that are considered genetically conserved, because mutations in those regions negatively affect the virus's ability to survive or replicate. In general, the *pol* gene is considered the most conserved gene and *env* is considered the least conserved gene likely due to *env* having a higher substitution rate. Therefore, analyses of regions other than *pol* may need to consider different genetic distance thresholds.

## HIV-1 Subtypes and Minority Strains

HIV-1 can be classified into four groups; of which M is associated with the majority of infections worldwide. Within group M, many distinct subtypes exist (e.g., A, B, C, D, F, G, H, J and K). The sequences within any one subtype are more similar to each other than to sequences from other subtypes. These subtypes represent different lineages of HIV, and have some geographical associations. Additionally, different subtypes can combine genetic material to form a hybrid virus, known as a “circulating recombinant form” (CRF).

Although most persons with HIV are infected with a single variant of HIV-1, rapid error-prone replication over time leads to HIV-1–positive individuals being infected with an enormous pool of genetically related strains called “quasispecies.” These quasispecies or variants are closely related viruses with different nucleotide sequences. Within an infected individual, HIV-1 diversity typically consists of a major, dominant strain and other less frequent genetic variants, which can change due to viral fitness, changes in immune response or drug pressure.

Minority strains are normally defined as those variants that are present in less than 20% of the total quasispecies pool. Sanger or bulk sequencing, the most common approach used for HIV drug-resistance testing in clinical settings, detects variants with a frequency of at least 20% of the total viral population. Hence, most minority strains will not be detected when testing for HIV drug resistance by using Sanger sequencing. The clinical significance of minority HIV-1 strains for development of drug resistance is not clear at the present time. About 10%–15% of newly diagnosed patients are infected with strains containing at least one drug-resistant mutation.

## HIV gene regions analyzed for detecting antiretroviral drug resistance

Testing for HIV drug-resistance mutations consists of sequencing only specific positions of the *pol* gene that encode enzymes targeted by antiretrovirals, including RT, protease (PR), and integrase (IN). Currently, the PR and RT sequences are analyzed in programs, such as Secure HIV-TRACE, to identify molecular clusters. Commercial, drug-resistance detection assays were developed using HIV-1 subtype B and may not perform well with other subtypes.

## Sanger Sequencing vs Next Generation Sequencing (NGS)

Sanger sequencing was developed by Dr. Frederick Sanger in the 1970s and involves the termination of DNA synthesis by selective incorporation of chain-terminating dideoxynucleotides by DNA polymerase during DNA replication, and separation and visualization of the resulting fragments by capillary electrophoresis and laser detection. Sanger or “bulk” sequencing was previously the most common method used for HIV drug-resistance testing in clinical settings. However, commercial laboratories are increasingly moving to NGS sequencing for clinical HIV drug resistance testing.

NGS, also referred to as deep sequencing or massively parallel sequencing, is based on the “sequencing by synthesis” principle where nucleotides incorporated into a strand of DNA provide a unique signal. The unique signal in most NGS platforms is a fluorescent molecule but can also be a change in pH. NGS can sequence myriad DNA fragments simultaneously in a short period of time and uses bioinformatics programs to piece together and analyze the synthesized sequences. These short DNA fragments are aligned, and from this alignment a ‘consensus sequence’ can be generated. In a consensus sequence, a single base is selected at each position. Such consensus sequences are what are currently reported to public health when labs use NGS to generate sequences, and consensus sequences have the same level

of information as traditional Sanger sequences. Raw next generation data, however, which includes all data from the hundreds or thousands of reads for a single specimen, contains substantially more information.

Several NGS platforms are available, each with their own synthesis and detection methods.

<b>Sanger Sequencing</b>	<b>Next Generation Sequencing</b>
DNA synthesis and signal detection are two separate processes and only one DNA strand (forward or reverse) can be read at a time	Synthesis and signal detection occur simultaneously by using multiple DNA templates
Cost per sample is more expensive; one sample per sequencing reaction	Cost is lower and process is faster; can sequence many samples simultaneously
No special bioinformatics infrastructure and storage capacity required	Bioinformatics infrastructure and storage capacity to store and analyze millions of sequence fragments is required
	Higher error rate but getting better
Sequence reads are longer (~700–900 bases per read per sample)	Sequence reads are shorter (< 400 bases per read depending on platform), but many more reads per sample per run are possible
Detects variants with prevalence of/greater than ~20%	Detect minority variants at a prevalence of/less than 1%
Most common method used for HIV drug-resistance testing in clinical settings	Mostly used in research settings

## Appendix C. Frequently asked questions about HIV-TRACE and transmission network analysis

Adapted from “Secure HIV-TRACE: a guide for public health departments to reconstructing HIV-1 transmission clusters,” courtesy of Joel Wertheim.

### Why pairwise alignment?

**Secure HIV-TRACE** was designed to detect transmission clusters by analyzing the 1497 nucleotide region spanning the HIV-1 *pro/rt* region common in public health surveillance activities, drug-resistance screening, and research studies. This genomic region is from a conserved genomic region with very limited length variation (unlike, say, *env*) across all major HIV-1 subtypes and circulating recombinant forms. The rarity of insertions and deletions permits robust pairwise alignment to a reference sequence. This approach is a timesaving measure compared with the more computational intensive approach of multiple sequence alignment, because it has linear complexity in the number of sequences; popular multiple sequence alignment algorithms all have superlinear complexity. **Secure HIV-TRACE** uses a modified version of the Smith-Waterman algorithm, which aligns nucleotide sequences by considering amino-acid translations of constituent codons; this approach allows us to make full use of amino-acid conservation to preserve alignment accuracy for divergent sequences (e.g., those from different subtypes).

### Why genetic distance?

Genetic distance provides a measure of epidemiological relatedness, because it increases as a function of time since transmission (in a linear fashion, as a first order approximation). This increase in genetic distance, due to an underlying molecular clock, provides a proxy for the amount of time that has passed since two viral strains diverged from one another. The molecular clock in HIV, however, is highly imprecise because of factors such as latency and natural selection due to immune escape and antiretroviral treatment. Furthermore, the virus evolves in both the donor and recipient, so the distance between two strains is not simply a multiplier for the time since transmission. However, genetic distance serves as a useful proxy for epidemiological relatedness.

### Why use a fixed distance cutoff?

Our recent work in named partners in New York City has demonstrated that genetic distance alone provides better insight into who are potential transmission partners than partner tracing alone. The distribution of pairwise distances among a population of named partners in New York City has the characteristic property of resembling a mixture of two distributions (see FIGURE 24): a component near 0 (i.e., closely/recently related sequences) and a component near 0.06 (i.e., two random sequences of the same subtype). Distance cutoffs of 0.01 to 0.02 segregate the two components nicely.

### What is TN93 genetic distance?

TN93 is the name of a nucleotide substitution model developed by Koichiro Tamura and Masatoshi Nei, published in 1993. Hence, TN93. Nucleotide substitution models are used in evolutionary analyses to correct for multiple substitutions (e.g., change from an A to a T then to C, before another genetic sequence has been sampled) and/or reversions (e.g., change from an A to a T back to an A, before another genetic sequence has been sampled) at a given site. Highly divergent sequences, with a greater

number of substitutions separating them, are more likely to require complicated evolutionary models to properly estimate the level of divergence. The simplest evolutionary model, JC69, has a single parameter governing mutation rates among different nucleotides, and assumes equal frequencies for all nucleotides. In contrast, a more complex evolutionary model like general time reversible model with gamma rate variation (GTR+  $\Gamma_4$ ) allows all nucleotide substitutions to occur at a unique rate, unique equilibrium base frequencies, and rate variation across sites. Importantly, over relatively short evolutionary distances (i.e., <0.05 substitutions/site), GTR+  $\Gamma_4$  does not improve distance estimation accuracy for simpler models like JC69, because not enough time has elapsed for a substantial number of multiple substitutions and/or reversions. In basic calculus terms, most curves resemble straight lines if you zoom in closely enough.

For **Secure HIV-TRACE**, we wanted an evolutionary model that optimizes both realism and computational efficiency. Simple models like JC69 and K2P (Kimura 2-parameter) have obvious shortcomings when applied to HIV: these models do not permit unequal nucleotide base frequencies, and HIV has notorious high frequencies of adenine (A) and low frequencies of uracil/thymine (U/T). The TN93 substitution model allows for unequal base frequencies and three different rates of substitutions between nucleotide bases: transitions between purines (i.e., A and G), transitions between pyrimidines (i.e., C and U/T), and transversions between purines and pyrimidines (e.g., A or U/T to C or G). Furthermore, distances estimated under TN93 can be represented by a closed form solution (i.e., computed without numerical optimization, simply from pairwise differences in nucleotide counts), which permits rapid computation of pairwise distances. More complex models require relatively expensive numerical optimization, especially because it will have to be done hundreds of millions or billions of times, to find all relevant distances. Over relatively short evolutionary distances (i.e., <0.05 substitutions/site), more complex models do not improve distance estimation accuracy. Therefore, when using genetic distances that are expected to be between 0.01 and 0.02 substitutions/site divergent to identify potential transmission partners, a substitution model more complicated than TN93 is not needed, and there are no appreciable computational savings to be had by using cruder models. As an example, our implementation can compute approximately 10 million TN93 distances per second on a single server node.

## Why not phylogenetics?

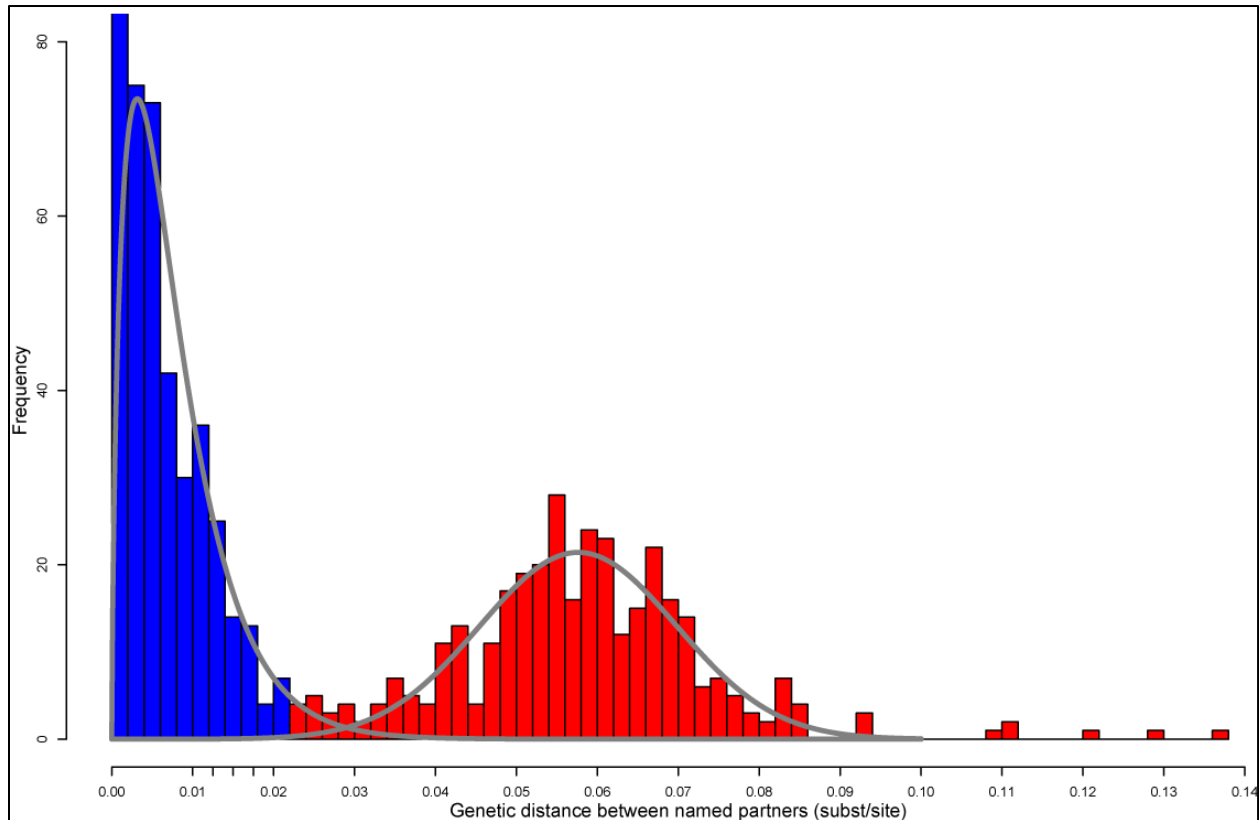
Phylogenetics is an extraordinarily powerful tool for understanding viral evolutionary history and dynamics, but phylogenetics says little about whether the relatedness of viruses A and B is epidemiologically meaningful. (For example, to say that two randomly selected subtype B sequences have a meaningful epidemiological linkage would be to say that we care about events that happened more than 50 years ago.) In fact, many HIV transmission network studies that used phylogenies also needed a genetic distance component.

A major problem with relying on phylogenetics to define what can be in a single cluster is that the models are highly contingent on the data and can change in counterintuitive ways. When the goal is tracking transmission network growth over time while adding more and more sequence data, this is a highly undesirable feature. Sequences that are clustered when using Secure HIV-TRACE will always be clustered by Secure HIV-TRACE if the analysis parameters stay the same; adding more data can only increase the size of clusters, not break them apart.

Another issue with the phylogenetic approach is that it takes a lot of computational time, especially for big datasets with tens or hundreds of thousands of HIV sequences. Currently almost half a million sequences are contained in the U.S. National HIV Surveillance database. And unlike a phylogenetic

approach which requires a complete re-analysis when a few new sequences are added, with our genetic distance approach, only the new sequences need to be considered, and all the previous computational work can be kept: like adding new pieces to a jigsaw puzzle.

**Figure 24. Distribution of genetic distances separating named partners in New York City. Potential transmission clusters are shown in blue. Random, within-subtype variation is shown in red.**



## What are ambiguous nucleotides? Or ambiguities?

When HIV infects an individual, it forms genetically diverse and potentially complex populations within that person. Currently, the sequence data reported to the National HIV Surveillance System are produced by using bulk Sanger sequencing, which produces a single genetic sequence representing this circulating population. If, for example, a thymine (T) nucleotide is contained at a given sequence site in at least 80% of the intra-host population, Sanger sequencing typically identifies a T at that site. However, when some intermixing strains have one nucleotide at a position and others have a different nucleotide at the same position, Sanger sequencing typically reports diversity at polymorphic sites as common nucleotide IUPAC ambiguity codes (e.g., R [A or G], Y [C or T], N [any nucleotide]). In standard phylogenetic inference, nucleotide ambiguities are “partially missing data” (e.g., Y is either C or T, but not A or G). When using pairwise distances (as in **Secure HIV-TRACE**) to construct genetic transmission networks, these nucleotide ambiguities have the potential to greatly complicate inference (see **FIGURE 25A**). The most conservative approach is to average the distance between ambiguities and resolved bases (e.g., Y is 0.5 differences from either C or T). But averaging ambiguities in transmission network analysis decreases the probability that sequences from chronically infected individuals—who are likely to have a more diverse viral population—will cluster in the network. Therefore, **resolving ambiguities** (so that Y would be 0 differences from either C or T, and 1 difference from A or G) appears to be an attractive option. However, if we are too permissive in our tolerance of ambiguities, unrelated viruses can become

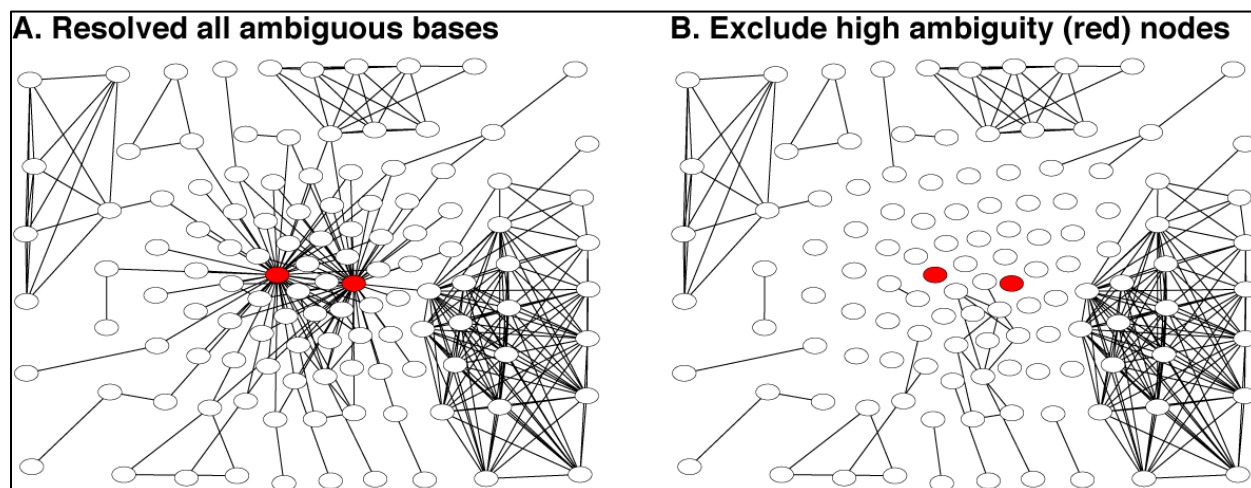


connected in our network. Variable sites are not uniformly distributed across the HIV genome. As a result, if ambiguities are resolved in the genetic distance calculation for a highly polymorphic sequence, this highly polymorphic sequence is likely to link to many “unrelated” viruses. The result is a large transmission cluster in which most sequences are connected to the high ambiguity sequence, but not to each other.

For example, if sequences from two people differ at 5% of sites, their viruses represent random intra-subtype variation and are not likely potential transmission partners. However, if within one of these people, most of this variation is polymorphic, and ambiguities are resolved in the genetic distance calculation, the genetic distance separating these viruses may fall below the distance threshold. Since variable sites are not uniformly distributed across the HIV genome, the highly polymorphic sequence is also likely to link to many other “unrelated” viruses as well. The result is a large transmission cluster in which most sequences are connected to a hub (the high ambiguity sequence) but not to each other.

In an example from the San Diego Primary Infection Cohort (**FIGURE 25A**), the genetic transmission network is affected by handling of nucleotide ambiguities. When ambiguities are fully resolved, the largest cluster in this cohort contains 119 people. However, when this cluster was mapped onto a maximum likelihood phylogenetic tree, its members are dispersed across the tree, encompassing the genetic diversity of the entire city of San Diego. Furthermore, the majority of nodes in the cluster are connected via two nodes acting as hubs (highlighted in red in **FIGURE 25**) which have 5.8% and 7.6% ambiguities and represent the two highest degree nodes in the network. The nodes connected through the spokes on these hubs rarely share an edge with each other. This feature, along with the phylogenetic dispersion, suggests that this cluster is an artifact of nucleotide ambiguity resolution. When these two hubs are excluded from the analysis, the cluster breaks apart, resulting in several distinct clusters and unconnected nodes (**FIGURE 25B**).

**Figure 25. Example in which two contaminant sequences with high numbers of nucleotide ambiguities (shown in red) can create artificial clustering among unlinked singletons and unrelated clusters. (A) The inferred cluster resolving all ambiguous nucleotides. (B) The same cluster where the two hubs (shown in red) are excluded from the analysis.**



Clusters that resemble **FIGURE 25A** should be interpreted with extreme caution. They are almost always spurious and the result of erroneous inference due to high levels of nucleotide ambiguities (or contamination with “reference” strains). **Secure HIV-TRACE** has been developed to minimize the chance of this artifact occurring.

## How does Secure HIV-TRACE handle ambiguous bases?

We recommend that nucleotide ambiguities be fully resolved when calculating genetic distance only when (i) the sequences have a low proportion of ambiguities or (ii) if the size of the dataset is small. When constructing a transmission network for datasets of thousands or tens of thousands of sequences, we recommend penalizing sequences with high levels of ambiguities. The “**Ambiguity Fraction**” parameter governs this penalty. The default “Ambiguity Fraction” value of 0.015 resolves the genetic distance between ambiguous nucleotides when calculating the distance between sequences with  $\leq 1.5\%$  ambiguities and averages the genetic distance between ambiguous nucleotides when calculating the distance between sequences with  $>1.5\%$  ambiguities.

Although not currently implemented in Secure HIV-TRACE, future versions will identify sequences with  $>5\%$  ambiguous nucleotides and flag them as problematic sequences and/or remove them from the analysis. This protocol follows the guide set forth by the Los Alamos National Laboratory (LANL) HIV Sequence Database ([https://www.hiv.lanl.gov/components/sequence/HIV/search/help.html#bad\\_seq](https://www.hiv.lanl.gov/components/sequence/HIV/search/help.html#bad_seq)). Extremely high proportions of ambiguities can be the result of poor quality sequencing, contamination, or dual infection. Including these sequences can adversely affect the performance of **Secure HIV-TRACE**.

## Why should I screen for laboratory contaminants?

Although the protocols for generating HIV-1 *pro/rt* genetic sequences are well validated, occasionally laboratory contamination with other genetic material is known to occur. This contamination is most often with the lab strain HXB2, but it can happen with any strain of HIV. Importantly, this contamination often results in a mixed sample where the resulting sequence is a combination of the isolate and the laboratory contaminant. This mixed sample often has high levels of ambiguous nucleotides and could compromise HIV-TRACE analysis if it were to be included, especially because mixing two unrelated strains will create ambiguities at many sites that tend to vary between strains, thereby enabling a “connection” through this sequence if ambiguous nucleotides are resolved (see above). Furthermore, if multiple contaminant sequences are included in the same analysis, they will erroneously be inferred to be part of the same cluster. Therefore, we screen every run for HXB2 linked sequences. Any sequence that links to HXB2 will be identified after the alignment phrase and excluded from further analysis.

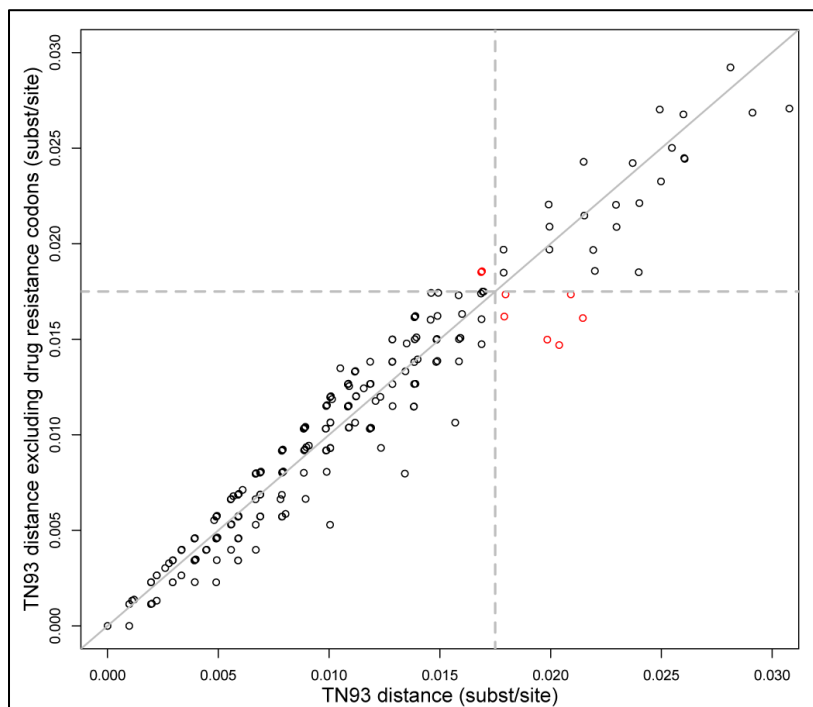
## What about drug-resistance–associated mutations (DRAMs)?

DRAMs often arise in HIV found in people taking antiretroviral therapy; they can be found in virus from both treatment-naïve and treatment-experienced people who were initially infected with a drug-resistant virus. DRAMs typically occur at a select set of sites that are not polymorphic in the absence of prior antiviral therapy. This type of convergent evolution at the amino acid-level has the potential to negatively affect phylogenetic inference. The genetic distance separating two viruses that undergone convergent evolution will theoretically be lower than two viruses that have not experienced convergent evolution. In practice, however, we find little to no effect of excising DRAM sites from network inference. Specifically, transmission networks built at the city, national, global level are robust to inclusion of DRAM sites. For example, when analyzing a cohort of named partner pairs in New York City, only a small fraction of partners become either linked or unlinked when DRAMs are excluded (red in **FIGURE 26**). Therefore, we do not recommend excising DRAMs from transmission network analyses using HIV-TRACE. An exception to this recommendation is for studies focusing on the effect



of DRAMs on network characteristics; in these instances, DRAM sites should be excised prior to network construction.

**Figure 26. Genetic linkage including/excluding codons associated with drug-resistance mutations in a New York City surveillance cohort. Nodes in red change linkage depending on inclusion/exclusion of DRAMs.**



## Appendix D. Additional resources

### Selected published articles that use HIV-TRACE analyses

- Wertheim JO, Leigh Brown AJ, Hepler NL, Mehta SR, Richman DD, Smith DM, Kosakovsky Pond SL. The global transmission network of HIV-1. *J Infect Dis* 2014;209(2):304–313.
- Little SJ, Kosakovsky Pond SL, Anderson CM, Young JA, Wertheim JO, Mehta SR, May S, Smith DM. Using HIV networks to inform real time prevention interventions. *PLoS One* 2014;9(6):e98443.
- Oster AM, France AM, Panneer N, Bañez Ocfemia MC, Campbell E, Dasgupta S, Switzer WM, Wertheim JO, Hernandez AL. Identifying clusters of recent and rapid HIV transmission through analysis of molecular surveillance data. *J Acquir Immune Defic Syndr* 2018. doi:10.1097/QAI.0000000000001856.
- Oster AM, Wertheim JO, Hernandez AL, Ocfemia MC, Saduvala N, Hall HI. Using molecular HIV surveillance data to understand transmission between subpopulations in the United States. *J Acquir Immune Defic Syndr* 2015;70(4):444–451.
- Whiteside YO, Song R, Wertheim JO, Oster AM. Molecular analysis allows inference into HIV transmission among young men who have sex with men in the United States. *AIDS* 2015;29(18):2517–2522.
- Wertheim JO, Oster AM, Hernandez AL, Saduvala N, Bañez Ocfemia MC, Hall HI. The international dimension of the U.S. HIV transmission network and onward transmission of HIV recently imported into the United States. *AIDS Res Hum Retroviruses* 2016;32(10–11):1046–1053.

## **National HIV Surveillance System (NHSS)**

### *Attachment 4(f)*

#### Instructions for Completing the Cluster Report

## Instructions for Completing the Cluster Report

### Overview

The Cluster Report is designed to assist jurisdictions with tracking the relevant steps of the roadmap for investigating and intervening in transmission clusters. See the guidance document ‘Detecting and Responding to HIV Transmission Clusters’ for more information. The Cluster Report is intended for use with molecular clusters that meet CDC’s definition of a national priority cluster, whether the cluster was first identified through local or through national analysis, as well as with additional clusters of concern identified through molecular analysis or alternative means (e.g., time-space analysis, partner services, or provider notification).

### Securely Submitting the Document

Jurisdictions should submit one Cluster Report (i.e. workbook containing all four tabs) per quarter for each cluster in which ongoing investigation and response activities are occurring. Only one tab should be filled out each quarter, depending on the stage of cluster detection and response. For more concerning clusters, jurisdictions are encouraged to submit the Initial Report form earlier, and/or provide CDC with a courtesy notification about the cluster. Subsequent quarters would only require updating the Cluster Follow Up Report and re-submitting the workbook until year-end and/or cluster closeout, in which the Annual/Closeout Report tab will be completed. Jurisdictions are encouraged to use the same workbook every time and simply update the information provided in the previous quarter using the Cluster Follow Up Report (or Annual/Closeout Report, as specified). Jurisdictions should continue to submit Follow Up and Annual/Closeout Reports every quarter and year, respectively, until investigation and response activities for the cluster conclude.

Cluster report forms must be submitted via secure transfer to CDC and must NOT be sent by email. Jurisdictions should submit their worksheets securely using the SAMS Cluster folder. Filepaths should follow this nomenclature so that they can easily be distinguished by CDC: “JURISDICTION ABBREVIATION\_CR\_CLUSTER ID\_REPORTING QUARTER AND YEAR.” For issues submitting files through SAMS, or to request SAMS access, please contact the SAMS helpdesk.

Note: While transfers via Cluster SAMS typically require encryption prior to upload, HICSB is currently conducting a pilot during which health departments can submit unencrypted Cluster Report Forms via Cluster SAMS. This pilot is currently from July 1 -October 1, 2020. Cluster Report Forms submitted without encryption must use a filename in the convention described in the prior paragraph – this is to ensure that the file can be identified and that only HICSB staff will access and download the file. \*\*Files other than cluster report forms sent through Cluster SAMS will still need to be encrypted.

Cluster Reports should be submitted by the final business day of the last month of each quarter (March, June, September, and December). A three-month window is provided after initial cluster detection before the Initial Report form is due, and Follow Up Report forms for the cluster are due quarterly. The

Annual/Closeout Report is due for all clusters detected 12 or more months prior on the last business day of December. Below is a breakdown of these timeframes for 2020:

- March 31, 2020: Submit the Initial or Follow Up Report for time-space or provider/DIS-identified clusters identified through December 31, 2019. Additionally, submit the Annual/Closeout Report for any clusters for which investigation and response activities were closed that quarter. **[Note: this deadline was extended to June 30, 2020 due to the COVID-19 pandemic.]**
- June 30, 2020: Submit the Initial or Follow Up Report for clusters identified through March 31, 2020. Additionally, submit the Annual/Closeout Report for any clusters for which investigation and response activities were closed that quarter. **[Note: this deadline was extended to September 30, 2020 due to the COVID-19 pandemic.]**
- September 30, 2020: Submit the Initial or Follow Up Report for clusters identified through June 30, 2020. Additionally, submit the Annual/Closeout Report for any clusters for which investigation and response activities were closed that quarter.
- December 31, 2020: Submit the Initial Report for clusters identified July 1, 2019 through September 30, 2020. Additionally, submit the Cluster Report (Annual/Closeout Report) excel workbook for all clusters identified through December 31, 2019 for which an active investigation or response is still ongoing. Submit the Follow Up Report for any other clusters identified between January 1, 2020 and June 30, 2020.

Instructions for completing each report are outlined below.

### Initial Cluster Report

#### *General Cluster Information*

- Complete the first two rows with the name of the reporting jurisdiction and the name of the person completing the Cluster Report. List the email address for the person completing the form. Use the dropdown menu option to indicate whether the jurisdiction is a low morbidity jurisdiction (defined as membership in the low morbidity jurisdiction workgroup) or not.
- **Question #1**, 'Date cluster first detected': Insert the date the cluster was first identified through any of the methods listed below in Question #5. If national molecular or national space-time analysis was used, insert the date your jurisdiction was notified of the existence of the cluster by CDC.
- **Question #2**, 'Date form completed': Insert the date the report was completed prior to submission to CDC. Note: Complete the Initial Cluster Report after the jurisdiction has gathered information for a preliminary desk review soon after cluster detection (Question #1). This does not have to be the same date as the date listed in Question #1. Enter the cluster into eHARS prior to completing this form.
- **Questions #3**, 'Local Cluster ID': Insert the local cluster ID entered into eHARS from the source that first detected the cluster (see 'Guidance on Entering Information Related to HIV Transmission Clusters Into eHARS' for more information on nomenclature for local cluster IDs).

- **Question #4**, 'National Cluster ID (if applicable): If the cluster has a national cluster ID (i.e. was detected by national molecular and/or national time-space analysis), enter that information in Question #4.
- **Question #5**, 'Initial cluster detection method that identified this cluster': Select the method that initially detected this cluster. Note: Only one option can be selected. This should match the information that is reported in eHARS.
  - Question #5a, b: For clusters identified by time-space analysis, please enter the county or other geographic area of the alert. If the geographic unit is at the county level, please enter the county in box 5a. If the geographic unit is not at the county level (for example, region, city, or other geographic area), please enter that geographic area in box 5b.
- **Question #6**, 'For clusters identified through molecular analysis, does this cluster meet national priority cluster criteria?': Select 'yes' or 'no' from the dropdown menu if the cluster was identified through molecular analysis. If the cluster was identified through another method, such as time-space analysis or provider notification, choose 'N/A'. Note: Molecular clusters meet national priority cluster criteria if defined at the 0.5% genetic distance threshold with at least 5 diagnoses in the past 12 months (or at least 3 diagnoses in the past 12 months for low morbidity jurisdictions).
- **Question #7**, 'Had this cluster been identified by any other method?': If the cluster was identified through multiple detection methods, select 'yes' and indicate all additional methods of cluster detection. Include the cluster ID and date detected for each.
- **Question #8**, 'Please indicate data reviewed for persons identified in the cluster': Select all sources of data that were reviewed for all persons in the cluster, including those in the transmission cluster as well as those in the risk network. Select 'yes' or 'no' from the dropdown menu options—do not leave any dropdown boxes blank. If 'yes' is selected as the option for 'other', use the cell to the right to specify the data source.

#### *Non-molecular clusters*

*(Complete this section only for clusters detected through other methods [i.e. time-space analysis or provider notification]. No further information on the Initial Report Form needs to be completed for non-molecular clusters.)*

- **Question #9**, 'Please describe the characteristics of the cluster that have raised concern': Provide a brief description of the aspects of the cluster that raised concern and led to the decision to report the cluster to CDC. For example, a sudden increase in diagnoses compared to baseline numbers that were detected through time-space analysis, an increase in IDU-associated HIV-infections, etc. **For time-space alerts, please note the geographic unit (i.e., county name) in which the cluster was identified here.**
  - Question #9a: Please describe the case definition you are using to determine which cases are included in this cluster (i.e., inclusion criteria for person, place, and time).
- **Question #10**, 'What is your current level of concern for this cluster?': Select 'High' (additional response is needed), 'Medium' (additional information about the cluster is needed), or 'Low' (no

additional investigation activities are needed at this time) from the dropdown menu. Note: It is not required to report clusters of low priority to the CDC unless the cluster meets national priority cluster criteria, or if enhanced response activities have been initiated.

- **Question #11**, 'Please briefly describe data review and investigation/response activities conducted to date for this cluster, and any notable findings.': Use this space to briefly describe any activities that have been undertaken so far related to cluster investigation and response, and any major findings associated with those activities (e.g. commonalities in demographic or transmission risk factors for cluster members, any common venues identified, high numbers of anonymous partners, etc.).

### *Molecular Clusters: Existing Data Review*

*(Complete this section only for clusters identified through analysis of HIV sequence data.)*

- **Question #12**, 'Number of people with HIV in the molecular cluster at time of detection who have a report of HIV in your jurisdiction': In cell 27D, specify the total number of HIV-positive persons known to be in the molecular cluster at the time of detection (i.e. only cases detected through molecular analysis). In cell 28D, specify the number of HIV-positive persons in the molecular cluster who were diagnosed in the 12 months prior to detection. Note: Include only those persons who have a report of HIV in your jurisdiction. (This number should capture any person in the cluster with a report in your jurisdiction's eHARS and should NOT be further restricted to only those residing in the jurisdiction at the time the form is completed). Diagnoses that had been made prior to cluster detection but were not yet known to be part of the cluster at the time the cluster was identified would not be included.
- **Question #13**, 'If additional people with HIV with a report of HIV in your jurisdiction have been added to the molecular cluster (based on any subsequent data analysis) since first identification, enter current numbers': Specify the total number of HIV-positive persons in the molecular cluster at the time of form completion (i.e. only cases detected through molecular analysis). Note: This number should include the overall number of cases reported in Question #12, plus any additional cases identified through subsequent analysis in cell 29D. In cell 30D, indicate the number diagnosed in the past 12 months from the total number reported in 29D. Include only those persons who have a report of HIV in your jurisdiction.
- **Question #14**, 'At what genetic distance threshold(s) is this cluster defined?': Select from the dropdown menu the option that correctly describes the genetic distance threshold used to define the molecular cluster: '0.5%', '1.5%', '0.5% with first degree links at 1.5%', or 'other (describe)'. If 'other' is selected, use the box to the right to describe the genetic distance threshold used. Refer to the guidance document 'Detecting and Responding to HIV Transmission Clusters' for considerations on what genetic distance threshold to use.
- **Question #15**, 'What is the time period of HIV diagnoses used to identify this cluster?': Select the option that correctly describes the time period of HIV diagnoses included in the molecular analysis: '3 years', 'all years' (greater than 3 years of diagnoses), or 'other'. If 'other' is selected, use the box to the right to describe the time period used. Note: Refer to the guidance document

‘Detecting and Responding to HIV Transmission Clusters’ for an explanation of CDC’s current approach of time periods of HIV diagnoses used in molecular analysis

- **Question #16**, ‘How many people with HIV in the molecular cluster reported in question 12 had been interviewed by partner services prior to cluster detection?’: Based on data review, list the number of molecular cluster members (reported in Question #12) that had been interviewed by partner services after HIV diagnosis and before identification as part of the cluster.
- **Question #17**, ‘How many people with HIV in the molecular cluster reported in question 12 were identified as connected to at least one other HIV-positive person in the molecular cluster through existing partner services data?’: List the total number of unduplicated molecular cluster members (reported in Question #12) that were known to be connected to at least one other person in the molecular cluster through existing partner services data. Note: Count each person that was named only once. For example, if Person A named Person B as a partner and Person B also named Person A as a partner, you would count both persons only once. Likewise, if Person A named Person B as a partner but Person B did not name Person A, you would still count both persons only once.
- **Question #18**, ‘Results of HIV testing of named partners of people with HIV in the molecular cluster’: Fill in testing information based on your existing data review for named partners of molecular cluster members. Note: Only include information about partners residing in your jurisdiction at the time of completion of the form. Do not include testing information on molecular cluster members even if they were named as partners by other members of the cluster. Only report numeric data in each of the cells provided (i.e. the number of new positives, the number of previous positives, the number not located, etc.). If your system had the functionality to do so, numeric information for 18a.-18l. can be pulled directly from your partner services database and shared as a separate excel attachment instead of reporting that information here.
  - For those who were tested (#18a-18f), indicate the number that newly tested as positive, negative or unknown testing results. New positive is based on patient report and no evidence of prior positive result in any state’s HIV surveillance system. If the number of acute positive persons, recent (not acute) positive persons, and PrEP referral information for negative persons is available, then report those as well. Note: If you are aware of testing outcomes for partners outside of your jurisdiction, these should still be counted in 18j so that field 19a is calculated correctly.
  - For those not tested (#18g-18l), indicate the number not tested classified according to the reason for why testing was not done. Note: Persons not tested due to being previously diagnosed with HIV infection should have been previously reported to any health department’s surveillance registry as being infected with HIV.
- **Question #19**, ‘How many additional persons have been claimed as partners (excluding other molecular members of the cluster) through DIS interview conducted prior to cluster detection?’: Report the de-duplicated number of individuals claimed as partners by molecular cluster members through interviews conducted prior to cluster identification. This number should be divided into four categories: 1) number of named partners residing in your jurisdiction, 2) number of named partners residing outside your jurisdiction, 3) number of marginal partners (e.g., some identifying information given, but not enough to locate the person), and 4) number of anonymous partners (e.g., no identifying information given). Note: If any of the molecular



cluster members named each other, this should be excluded from the total. Molecular cluster members that named each other are accounted for in Question #17. Values for Questions #19a (named partners residing in your jurisdiction) and #19b (named partners residing outside your jurisdiction) will be auto-filled based on information provided in Question #18 above.

- **Question #20**, 'Size of transmission cluster in your jurisdiction as identified through review of available data': The value for Question #20 will be auto-filled from Questions #13, 18a and 18g.
- **Question #21**, 'How many people with HIV in the transmission cluster reported in question 20 have evidence of recent viral suppression (most recent viral load <200 cp/mL and occurred in the past 12 months)?': Indicate the number of transmission cluster members (molecular cluster members plus known HIV-positive partners) with evidence of recent viral suppression (most recent viral load <200 cp/mL and occurred in the past 12 months). After cluster ID information is entered into eHARS following the CDC guidance for this variable, this information can be pulled directly from eHARS.
- **Question #22**, 'Number of persons in the risk network in your jurisdiction identified through review of available data who are not known to be HIV infected': The value for Question #22 will be auto-filled based on information provided in Question #18. Note: This should equal the number of HIV-negative persons and persons with unknown HIV status reported in #18d, 18f, 18h, 18i, and 18l.
- **Question #23**, 'If the transmission cluster or risk network includes persons outside of your jurisdiction, please describe any collaboration efforts with the other jurisdictions involved.': Use the box to the right to describe any collaboration efforts that have taken place to-date with outside jurisdictions regarding cases in the cluster.

#### *Existing Data Review: Cluster-level characteristics, commonalities and summary*

*(Complete this section only for clusters detected through molecular analysis.)*

- **Question #24**, 'Were any common venues or physical sites identified?': Indicate whether any common venues or physical sites were identified among persons in the cluster through existing data review. If you select 'yes', use the box to the right to describe.
- **Question #25**, 'Were any common virtual sites identified?': Indicate whether any common virtual sites or apps were identified among persons in the cluster through existing data review. If you select 'yes', use the box to the right to describe.
- **Question #26**, 'What other factors identified might be associated with increased transmission in this cluster?': Use the box to the right to describe any factors that you have identified through data review and investigation efforts to-date that may be associated with increased transmission in this cluster.

#### *Key findings from review of partner services, surveillance, and other available data*

*(Complete this section only for clusters detected through molecular analysis.)*

- **Question #27**, 'Please provide a brief, narrative summary of key findings based on existing data review.': Use the box to the right to report key findings and other observations not captured above from your review of partner services, surveillance, and other available data.
- **Question #28**, 'Based on your initial review of the data, what is your level of concern for this cluster?': Indicate your level of concern about this cluster based on initial data review: 'High' (additional response is needed), 'Medium' (additional information about the cluster is needed), or 'Low' (no additional investigation activities are needed at this time).

### Cluster Follow Up Report

*(Complete this form quarterly for all clusters, regardless of method of detection, beginning with the quarter after the Initial Cluster Report form has been submitted.)*

- Complete the first two rows with the name of the jurisdiction (this will autofill based on the response provided in the Initial Cluster Report form) and the name of the person completing the Cluster Report. The person completing the form should also list their contact information (email). There is also a dropdown menu option to indicate whether the jurisdiction is a low morbidity jurisdiction (defined as membership in the low morbidity jurisdiction workgroup) or not. Note: This value will autofill based on the response you provided in the Initial Cluster Report form.
- **Question #1**, 'Date form completed': Fill in the final date the report was completed prior to submission to CDC.
- **Questions #2**, 'Local Cluster ID ', and **#3**, 'National Cluster ID (if applicable)': In completing Question #2, use the local cluster ID entered into eHARS from whichever source first detected the cluster (see 'Guidance on Entering Information Related to HIV Transmission Clusters Into eHARS' for more information on nomenclature for local cluster IDs). If the cluster has a national cluster ID (i.e. was detected by national molecular and/or time-space analysis), enter that information in Question #3. Note: These values will autofill based on the response you provided in the Initial Cluster Report form.
- **Question #4**, 'Are response activities for this cluster currently ongoing?': Select 'yes' or 'no' from the dropdown menu. If you answer 'no', DO NOT fill out this form. Complete and submit the Annual/Cluster Closeout Form instead.
- **Question #5**, 'Current number of persons in the transmission cluster in your jurisdiction': Indicate the total number of persons in the transmission cluster (i.e. molecular cases plus known HIV-positive partners) residing in your jurisdiction at the time of completion of the form. After cluster ID information is entered into eHARS for all current cases following the CDC guidance for this variable, this information can be pulled directly from eHARS. Note: For non-molecular clusters, report the number of persons who met the case definition for this cluster.
- **Question #6**, 'Current number of persons in the risk network in your jurisdiction who are not known to be HIV positive': Indicate the total number of persons in the risk network not known to be HIV positive who are residing in your jurisdiction at the time of completion of the form. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other

persons known to be connected to members of the cluster who do not have evidence of HIV infection.

- **Question #7**, 'Has testing or re-testing been conducted for any persons who were not known to be HIV positive at the time of identification as part of the risk network?': Use the dropdown menu to the right to select 'yes' or 'no' to indicate whether HIV testing or re-testing has been conducted for persons not known to be HIV positive at the time of identification as part of the risk network to-date. Note: For non-molecular clusters, this refers to testing/re-testing efforts among HIV-uninfected partners or other persons known to be connected to members of the cluster who did not have evidence of HIV infection at the time of identification.
- **Question #8**, 'Of persons who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network, what are the results of testing or re-testing efforts to date?': This question consists of three components, and should only be completed if the answer to Question #7 is 'yes'. For all, only list the number of persons who were not known to be HIV positive at the time of identification as part of the risk network who are currently residing in your jurisdiction. Information can be pulled directly from your partner services database and provided as a separate excel attachment rather than reporting that information here, if your system has the functionality to do this. Note: For non-molecular clusters, this refers to testing/re-testing efforts among HIV-uninfected partners or other persons known to be connected to members of the cluster who did not have evidence of HIV infection at the time of identification.
  - For #8a, indicate the total number of persons in your jurisdiction who have been tested (for persons with HIV-unknown status) or re-tested (for HIV-negative persons) to date, regardless of whether or not they were tested within 6 months of identification as part of the risk network.
  - For #8b, indicate the number of persons in your jurisdiction who newly tested positive as a result of testing (for persons with HIV-unknown status) or re-testing (for HIV-negative persons) efforts to-date, regardless of whether or not they were tested within 6 months of identification as part of the risk network.
  - For #8c, indicate the total number of HIV-negative persons in your jurisdiction newly referred for PrEP, regardless of whether or not they were referred within 6 months of identification as part of the risk network.
  - **\*\*Note:** while this question does not specifically capture the number of persons who were lost to follow up or refused testing or re-testing efforts, these challenges can be described in the narrative response for Question #9, below.
- **Question #9**, 'Please describe any challenges you have encountered in promoting viral suppression among persons in the transmission cluster, or in conducting testing/re-testing and PrEP referral among persons in the risk network': Use the narrative box provided to the right to describe any challenges you have encountered to-date in promoting viral suppression, conducting testing/re-testing activities, or referring persons to PrEP. Note: For non-molecular clusters, this refers to HIV-positive persons who met the case definition for this cluster as well as HIV-uninfected partners or other people known to be connected to cluster members who did not have evidence of HIV infection at the time of identification.
- **Question #10**, 'Since the time of cluster detection, have any of the following investigation and/or intervention activities been conducted': Use the dropdown menu choices below to

indicate in 9a-9g whether specific cluster investigation and intervention activities have been conducted to-date. Choose 'yes' or 'no' for each question; do not leave questions blank.

- If the answer to #9h is 'yes', use the box to the right to describe what types of messaging activities have been conducted to-date.
  - If the answer to #9g is 'yes', use the box to the right to describe what additional investigation and intervention activities have been conducted to-date.
- **Question #11**, 'What is your current level of concern for this cluster?': Indicate your current level of concern about this cluster using the dropdown menu options: 'High' (additional response is needed), 'Medium' (additional information about the cluster is needed), or 'Low' (no additional investigation activities are needed at this time).
- Space is provided in Question #12 to report key findings and other observations not captured above.

### Annual/Cluster Closeout Report

*(Complete this report annually, and also submit this form as a final report during the quarter in which you closed investigation and response activities for the cluster. You do not need to submit a Follow Up Report during the same quarter; the information in the Annual/Closeout Report supplants the information in the Follow Up Report.)*

- Complete the first two rows with the name of the jurisdiction (this will autofill based on the response provided in the Initial Cluster Report form) and the name of the person completing the cluster investigation worksheet. The person completing the form should also list their contact information (email). There is also a dropdown menu option to indicate whether the jurisdiction is a low morbidity jurisdiction (defined as membership in the low morbidity jurisdiction workgroup) or not.
- **Question #1**, 'Date form completed': Fill in the final date the report was completed prior to submission to CDC.
- **Questions #2**, 'Local Cluster ID', and **#3**, 'National Cluster ID (if applicable)': In completing Question #2, use the local cluster ID entered into eHARS from whichever source first detected the cluster (see 'Guidance on Entering Information Related to HIV Transmission Clusters Into eHARS' for more information on nomenclature for local cluster IDs). If the cluster has a national cluster ID (i.e. was detected by national molecular and/or time-space analysis), enter that information in Question #3. Note: These values will autofill based on the response you provided in the Initial Cluster Report form.
- **Question #4**, 'Are response activities for this cluster currently ongoing?': Select 'yes' or 'no' from the dropdown menu. If you answer 'no', you must also complete Questions #5 and #7 (otherwise, you should skip those questions).
- **Question #5**, 'Date cluster investigation and response activities closed': Enter the date in which investigation and response activities ceased and your jurisdiction determined that the cluster response should be closed. This question should only be answered if you responded 'no' to Question #4 above; otherwise, leave the cell blank or put 'N/A.'

- **Question #6, 'Size of cluster at closeout/current cluster size':** If you are filling out this form as an annual report, indicate the size of the cluster at the time of completing the report. If you are filling out this form at cluster closeout, indicate the size of the cluster at the time your jurisdiction decided to close cluster investigation and response activities (Question #5 above). The total number should be divided into two categories: transmission cluster members (molecular cluster members plus known HIV-positive partners) reported by and residing in your jurisdiction and risk network members (not known to be HIV-infected) residing in your jurisdiction. Note: For non-molecular clusters, report the number of persons who met the case definition for this cluster in cell D7. In cell D8, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster who do not have evidence of HIV infection.
- **Question #7, 'Reason(s) for closeout':** Briefly describe the reason for closing out the cluster investigation and response. Complete this question only if the answer to Question #4 is 'no'; otherwise, leave blank or put 'N/A.'
- **Question #8, 'Since the time of cluster detection, have any of the following investigation and/or intervention activities been conducted':** Use the dropdown menu choices below to indicate in 8a-8g whether specific cluster investigation and intervention activities have been conducted to-date. Choose 'yes' or 'no' for each question; do not leave questions blank.
  - If the answer to #8h is 'yes', use the box to the right to describe what types of messaging activities have been conducted to-date.
  - If the answer to #8g is 'yes', use the box to the right to describe what additional investigation and intervention activities have been conducted to-date.
- **Question #9a, 'How many persons in your jurisdiction did not have evidence of viral suppression at the time of identification as part of the cluster?':** Report the total number of persons in the cluster currently residing in your jurisdiction that did not have evidence of viral suppression at the time of identification as part of the cluster, regardless of when or how the person was identified as part of the cluster. (Viral suppression is defined as most recent viral load <200 cp/mL and occurred in the past 12 months). This information can be pulled directly from eHARS and submitted as a separate attachment if desired. Note: For non-molecular clusters, report the number of persons who met the case definition for this cluster who did not have evidence of viral suppression at the time of identification as part of the cluster.
  - **Question #9b, 'Among persons who did not have evidence of viral suppression at the time of identification as part of the cluster (9a), how many achieved viral suppression within six months?':** Report the number of persons in Question #9a who achieved viral suppression within six months of identification as part of the cluster. This information can be pulled directly from eHARS and submitted as a separate attachment if desired. Note: For non-molecular clusters, report the number of persons who met the case definition for this cluster in Question #9a who achieved viral suppression within six months of identification as part of the cluster.
- **Question #10a, 'How many persons in your jurisdiction were HIV-negative or had unknown HIV status at the time of identification as part of the risk network?':** Report the total number of persons residing in your jurisdiction who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network, regardless of when or how the person was identified as part of the risk network. Note: For non-molecular clusters, report the number of

HIV-uninfected partners or other persons known to be connected to members of the cluster who did not have evidence of HIV infection at the time of identification.

- **Question #10b**, 'Of persons who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network (10a), how many were tested/re-tested within 6 months?': Report the number of persons in Question #10a who were tested (if HIV status was unknown at identification as part of the risk network) or re-tested (if HIV status was negative at identification as part of the risk network) within 6 months. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster who were tested (for persons with unknown HIV status) or re-tested (for HIV-negative persons) within 6 months.
- **Question #10c**, 'Of persons who were HIV-negative or had unknown HIV status at the time of identification as part of the risk network (10a), how many were tested/re-tested at greater than 6 months?': If any persons in 10a were tested or re-tested more than 6 months after identification as part of the risk network, report that number here. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster who were tested (if HIV status was unknown at identification as part of the risk network) or re-tested (if HIV status was negative at identification as part of the risk network) greater than 6 months after identification.
- Information for Questions #10a-10c can be pulled directly from your partner services database and provided as a separate excel attachment rather than reporting that information here, if your system has the functionality to do this.
- **Question #11**, 'Results of testing and re-testing for persons in 10a': Fill in testing/re-testing results for the persons reported in #10a above. With the exception of 11j, only include information on persons residing in your jurisdiction. Only report numeric data in each of the cells provided (i.e. the number of new positives, the number of previous positives, the number not located, etc.). Note: Information for 11a.-11l. can be pulled directly from your partner services database and provided as a separate excel attachment rather than reporting that information here, if your system has the functionality to do this.
  - For those who were tested or re-tested (#11a-11f), indicate the number that newly tested as positive and those who tested as negative, as well as any with unknown testing results. If the number of acute positive persons and recent (not acute) persons is available, report those as well. Report the total number referred for PrEP (regardless of whether they were referred within 6 months) in 11e.
  - For those not tested (#11g-11l), indicate the number not tested classified according to the reason for why testing was not done. Persons who were initially not known to be infected with HIV who are now reported as being previously diagnosed with HIV infection should have been previously reported to a health department's surveillance registry as being infected with HIV.
- **Question #12a**, 'How many persons in your jurisdiction were HIV-negative and not on PrEP at the time of identification as part of the risk network?': Report the total number of persons residing in your jurisdiction who were HIV-negative and not on PrEP at the time of identification as part of the risk network, regardless of when or how the person was identified as part of the

risk network. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster who did not have evidence of HIV infection at the time of identification.

- **Question #12b**, 'Of all persons who were HIV-negative and not on PrEP at the time of identification as part of the risk network (12a), how many were screened for PrEP within 6 months?': Report the total number of persons from Question #12a who were screened for PrEP within 6 months of identification as part of the risk network. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster from Question #12a who were screened for PrEP within 6 months of identification.
- **Question #12c**, 'Of all persons who were screened for PrEP within 6 months (12b), how many were determined to be eligible?': Report the number of persons from Question #12b who were determined to be eligible for PrEP within 6 months. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster from Question #12b who were determined to be eligible for PrEP within 6 months.
- **Question #12d**, 'Of all persons who were eligible for PrEP within 6 months (12c), how many were referred?': Report the number of persons from Question #12c who were referred for PrEP within 6 months. Note: For non-molecular clusters, report the number of HIV-uninfected partners or other persons known to be connected to members of the cluster from Question #12c who were referred for PrEP within 6 months.
- **Question #13**, 'What key lessons were learned through the course of investigating this cluster?': Provide a brief description using the box to the right regarding lessons that were learned through investigating and responding to this cluster.
- **Question #14**, 'Please describe the impact of cluster investigation and response activities on current health department policies and processes': Use the space to the right to comment on ways in which cluster investigation and response activities have impacted your health department's policies and processes. Examples of topics to include here include (but are not limited to) the following: whether any enhancements were made to regular HIV prevention and treatment processes such as provision of case management services or expansion of PrEP resources, whether communication within the health department or interactions between local and state health departments changed, whether the cluster was used to advocate for policy changes, whether additional resources were required to respond to this particular cluster, etc.
- **Question #15**, 'Briefly describe your current level of concern for this cluster and why ongoing response is still needed. If the cluster response has been closed, instead describe how you will continue monitoring the cluster for future growth.': Provide a brief description of your current level of concern for the cluster and why ongoing response is still needed, if you are submitting this form as an annual report. Otherwise, if you are submitting this form as a cluster closeout, indicate how you plan to continue monitoring the cluster for future growth. Indicate the person(s) who will be responsible for this activity and their role(s), and how CDC will be notified if the cluster experiences additional growth in the future.

## Summary Tables

The Cluster Report form contains a Summary Tables tab which is auto-populated based on responses to questions in the previous tabs. No action is required to complete this tab, provided you have responded to all questions on the preceding report forms. This information may be useful for your jurisdiction in planning your cluster response activities and monitoring the progress of key outcome measures on a cluster level.